Introduction: Why Neuromodulation for Spinal Cord Injury (SCI)

Spinal cord injury often cuts off the communication between the brain and the body, leading to paralysis and loss of bodily functions. For decades, the outlook for chronic SCI recovery was limited. **Neuromodulation and neurostimulation** – using electrical, magnetic, or other energy to modulate the nervous system – have emerged as game-changing approaches. These technologies aim to **reawaken dormant neural circuits** and help reconnect the brain with muscles or organs below the injury. Unlike past “cures” that focused on nerve regrowth (which remains very challenging), neuromodulation provides *practical, technical strategies to improve function* even without fully healing the spinal cord. Today, a diverse toolkit is being developed: from **spinal cord stimulators** that revive walking movements, to **functional electrical stimulation (FES)** that activates paralyzed muscles, to **brain implants and brain-computer interfaces (BCIs)** that decode thoughts or stimulate circuits, and even **ultrasound and magnetic stimulation** approaches. This report will delve into four major areas of neuromodulation for SCI – painting a comprehensive picture of the science, the key players (companies, labs, clinics), the current clinical status, and how close these advances are to everyday use. Throughout, we maintain a balance of hope and honesty, highlighting both remarkable breakthroughs and the realistic limitations and timelines.

Why now? In the last 10–15 years, there has been an explosion of research and investment in SCI neuromodulation. Multiple high-profile scientific studies have shown that stimulating the nervous system can yield recovery of functions once deemed permanently lost (walking, hand movement, blood pressure control, etc.). This momentum has given rise to startups, clinical trials, and even early commercial treatments. People with SCI and their families have more reason for hope than ever before – but it’s important to understand **which approaches are proven in humans, which are still experimental, and how they might eventually combine**. In the sections below, we explore each domain of neuromodulation in depth.

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1. Spinal Cord Stimulation (SCS) for Movement and Function

Overview: *Spinal cord stimulation (SCS)* involves delivering electrical pulses to the spinal cord, typically via electrodes placed on or near the cord. In SCI, SCS is used to **excite neural circuits below the injury**, making them more receptive to signals and enabling movements or functions that were lost. There are two main forms: **epidural SCS**, with an electrode array implanted on the dura (outer surface of the cord); and **transcutaneous SCS**, with electrodes placed on the skin over the spine (non-invasive). Unlike FES (which directly stimulates muscles – covered in Section 2), SCS targets the spinal cord’s own networks (like central pattern generators and reflex pathways). By tuning stimulation parameters, SCS can amplify weak voluntary signals or even generate rhythmic movements like stepping. Over the past decade, SCS has helped some individuals with chronic paralysis stand and take steps, regain some hand movement, and even improve blood pressure regulation. Below, we profile the major organizations and programs driving SCS for SCI, covering who they are, their origins, key people, accomplishments, and plans.

Onward Medical

Who they are: Onward Medical (ONWARD) is a medical technology company (publicly traded on Euronext: ONWD) focused on spinal cord neuromodulation therapies for restoring function after SCI. It's essentially a *startup-turned-scaleup* that merged cutting-edge neuroscience with a commercial strategy. Onward is headquartered in the Netherlands (Eindhoven) with significant operations in Lausanne, Switzerland (it has roots in the Swiss research ecosystem). It began as an EPFL spin-off – originally known as GTX Medical – and later merged with an American startup (NeuroRecovery Technologies) around 2019 [1]. After the merger, the combined entity rebranded as "Onward" and went public in 2021, raising over $100 million to fund development [2].

Background & origins: Onward's founding story traces back to two pillars of SCI research. One pillar was **GTX Medical**, co-founded by neuroscience professor **Grégoire Courtine** (EPFL) – known for pioneering epidural stimulation in animals and humans – along with collaborators in Europe. The other pillar was **NeuroRecovery Technologies (NRT)**, a California startup co-founded by **Dr. Reggie Edgerton** of UCLA (a legendary SCI researcher) and colleagues including **Susan Harkema** (University of Louisville) and **Yury Gerasimenko**. NRT initially aimed to build improved implantable stimulators for SCI [3] [1]. In 2015, NRT also developed a transcutaneous stim device after discovering that skin-surface stimulation could produce meaningful effects [4]. Facing funding challenges, NRT joined forces with GTX in 2019, marrying European and US innovations [1]. This created Onward Medical, which has since become a frontrunner in SCS for SCI.

Key people: Dave Marver is Onward's CEO – a medtech veteran who joined in 2020 and led the IPO in 2021 [5] [2]. Scientific co-founders include **Grégoire Courtine, PhD**, who leads NeuroRestore at EPFL (see NeuroRestore below) and serves as a scientific advisor, and **Prof. Reggie Edgerton**, whose decades of spinal stimulation research laid the groundwork (Edgerton is often called the "godfather of spinal cord stimulation" [6]). The company's board includes industry figures like **Rob ten Hoedt** (Chairman) and others from the neurotech field [7]. Onward's R&D team and advisors feature neuroscientists, engineers, and clinicians from the EPFL-Lausanne network and beyond.

Past work: Prior to the merger, the components of Onward had already achieved notable firsts. In 2018, Courtine's team in Switzerland (using what became Onward's tech) enabled three men with chronic paraplegia to walk with support using an implanted epidural stimulator, combined with intensive rehab – a result published in *Nature* that grabbed worldwide attention. In the US, researchers affiliated with NRT (Harkema's team in Louisville) had earlier demonstrated the first ever human epidural stimulation success in 2009–2011: a young man named Rob Summers (with complete motor paralysis) was able to stand and move his toes after an epidural implant [3]. NRT and UCLA also explored transcutaneous stimulation; by the late 2010s, small studies showed that non-invasive stimulation could enable some voluntary movement and "switch on" the core trunk musculature in participants (one subject said it "felt like the core of their body was turned on" [8]). These promising "pilot" trials de-risked the technology [9] and paved the way for Onward's larger studies. Additionally, Onward benefited from intellectual property from research institutions – it has nearly 300 patents (licensed or in-house) covering various aspects of spinal stimulation [10].

Current work: Onward has two main therapy platforms in advanced stages: **ARC-EX** (an external, non-invasive stimulator) and **ARC-IM** (an implantable stimulator system). Both deliver what Onward calls "ARC Therapy," which is a *targeted stimulation regimen* tailored for specific functional outcomes [11].

- **ARC-EX:** This is a wearable stimulator that delivers transcutaneous (through the skin) spinal cord stimulation via surface electrodes. It's paired with a simple tablet interface for therapists. ARC-EX is mainly aimed at improving *upper-body function* (arm and hand) in people with cervical SCI.

Onward completed a pivotal trial called **Up-LIFT** with 65 participants with chronic tetraplegia using ARC-EX therapy for hand/arm rehabilitation [12]. The results, published in *Nature Medicine* in 2023, were positive: the trial met its endpoints, with about 90% of participants seeing improvements in arm/hand strength or function, and significant gains in sensation as well [12]. For example, many participants improved their grasp strength or dexterity enough to perform daily tasks that were previously impossible [13]. Notably, benefits were observed even in people up to 34 years post-injury [13]. ARC-EX is non-invasive and session-based (the user attends stimulation-assisted training sessions). It received **FDA Breakthrough Device Designation** and, as of 2023, Onward was anticipating FDA approval. Indeed, ARC-EX obtained regulatory clearance in the U.S. in 2023 for improving upper limb function in chronic SCI. The company has already begun commercialization: by 2025 there was "robust demand" for ARC-EX systems in the U.S. rehab centers, according to investor updates [14]. This suggests ARC-EX is on the cusp of being integrated into routine therapy for SCI in specialized clinics.

- **ARC-IM:** This is an implanted epidural stimulation system, composed of a proprietary electrode array and an implantable pulse generator (IPG). Unlike using repurposed pain stimulators, Onward's implant is purpose-built for SCI needs. One version of ARC-IM targets **lower-limb movement** (enabling standing, stepping, and possibly trunk control). Another critical application is **autonomic regulation:** ARC-IM is being designed to address blood pressure instability, particularly *neurogenic orthostatic hypotension* (chronic low blood pressure that causes dizziness and fatigue) and *autonomic dysreflexia* (dangerous blood pressure spikes). In collaboration with academic partners, the company identified a specific region of the spinal cord (in the upper thoracic segments) as a "hemodynamic hotspot" – stimulating this area can stabilize blood pressure [15] [16]. By 2023, an ARC-IM prototype for blood pressure, with uniquely shaped electrodes targeting that hotspot, was tested in 14 individuals across Switzerland, the Netherlands, and Canada, showing it could restore normal blood pressure in people with severe SCI-related hypotension [17] [18]. Participants reported feeling more alert and energetic when the stimulator was on, and less "brain fog," as blood pressure stayed in a healthy range [19]. Building on these results, in 2025 Onward received FDA IDE approval to launch a large **pivotal trial** of the ARC-IM therapy for blood pressure, expected to involve ~20 centers in North America and Europe [20]. In terms of mobility, an earlier study ("STIMO") in 2018 had shown an implanted stimulator (the precursor to ARC-IM) enabled several paraplegic individuals to take steps and improve weight-bearing when stimulation was on, and some voluntary improvement remained even with stim off after extensive rehab – indicating plasticity was induced. Now, Onward is running trials aiming at eventual approval of ARC-IM for **walking restoration** in combination with rehabilitation. According to CEO Dave Marver, the target timeline is commercial launch of the implantable platform around 2024–2025 [21]. Indeed, the ARC-IM stimulation for movement and blood pressure has also earned FDA Breakthrough Device status [22].

Additionally, Onward (in partnership with research institutes) is exploring **brain-computer interface (BCI) technology** to link the brain to the spinal stimulator (dubbed "ARC-BCI"). In May 2023, a breakthrough case showed a man with chronic tetraplegia was able to walk using a BCI that detected his intention to move and then triggered ARC-IM stimulation in his spinal cord – a so-called "digital bridge" between brain and spine [23] [24]. This was achieved by EPFL, CEA and others, but Onward is closely involved in turning this into a product; a European project is funding development of a **commercial version of the brain-spine interface** with Onward's participation [25]. While still experimental, it hints at a future where Onward's stimulators could be paired with brain implants for volitional control of movement (more on BCIs in Section 5).

Major milestones & results: Onward's approach has yielded several *landmark results in SCI*. Summarizing the big ones:

- *Motor function:* Multiple individuals with chronic paralysis (years after injury) have regained the ability to step, with support, when epidural stimulation is on. In some cases, after months of training with stimulation, they recovered some voluntary movement even with the stim off – suggesting lasting reorganization of neural pathways. For example, in Nature 2018, Courtine/Onward's team reported 3 men with complete paralysis (AIS A/B) who, after ARC-IM stimulation and rehab, walked over ground with assistive devices and had improved muscle control even without stimulation. In 2022, another study showed improved trunk and balance control using specific stimulation programs targeting the trunk musculature in 9 individuals. These studies collectively overturned the dogma that chronic SCI means no further recovery is possible. However, it's important to note that the recovered walking is not "normal" walking – typically it's slow and requires walker support – and it works best in people with some spared pathways (e.g. incomplete injuries). Still, the gains in independence (like standing to reach objects, or walking short distances at home) are life-changing for those individuals. - *Upper limb and hands:* The Up-LIFT trial (65 people with cervical injuries) demonstrated significant improvements in grip strength, arm movement and sensation with non-invasive ARC-EX therapy [12]. One high-profile result from earlier studies was a man with C4 tetraplegia who improved from being unable to grasp at all to being able to grasp and manipulate objects after a few months of transcutaneous stimulation therapy. The peer-reviewed data from Up-LIFT now solidify that **external stimulation combined with training can yield functional hand/arm gains** in a majority of chronic tetraplegic patients [12]. - *Blood pressure/ autonomic:* In 2021–2022, Onward and collaborators published in *Nature Medicine* the first successful chronic implant to **treat low blood pressure in SCI**. By stimulating the T2-T3 spinal cord region (hemodynamic hotspot), they kept blood pressure stable in people who used to have daily dizziness and blackouts [17] [18]. Participants like "Julie" in the study said "I have my life back… now I can go back to school" after the implant [26]. This work addresses a *lesser-known but critical issue* for many with high SCI – and it marked the first targeted neuromodulation therapy for an autonomic problem in SCI, beyond motor functions. Another autonomic benefit observed (both in Lausanne's work and at Louisville) is that epidural stimulation can reduce episodes of autonomic dysreflexia (dangerous BP spikes) by moderating the spinal reflexes that overshoot.

Future plans for SCI: Onward's stated vision is **to make spinal stimulation part of standard care for SCI**. In interviews, CEO Dave Marver emphasizes creating a *new therapy category* that rehab centers and surgeons will adopt routinely [27] [28]. The roadmap is to roll out ARC-EX in rehabilitation clinics (since it's non-surgical) to build awareness and clinician acceptance, and then introduce ARC-IM for more advanced restoration [29]. By 2025, Onward expected to be in pivotal trials for ARC-IM and aiming for regulatory approvals possibly in 2025–2026 [21]. They have also forged partnerships (e.g., with rehabilitation hospitals and with tech companies) to ensure training and support for the therapy. The **long-term vision** is that a person with SCI might receive an *implanted stimulator a few months after injury*, undergo intensive rehab with stimulation to regain mobility and health, and continue to use the implanted device chronically (similar to how pacemakers or pain stimulators are used). Onward is also pursuing indications in other conditions (like Parkinson's disease gait problems), but for SCI specifically, they are focused on three domains: improving upper limb function, enabling mobility, and stabilizing blood pressure [30]. They've hinted at combining their stimulation with other tech like BCIs (as mentioned) and *closed-loop control* (future versions of implants might adjust stimulation in real-time based on sensor inputs or the user's attempted movements). Regulatory-wise, they have Breakthrough Device status (which should expedite FDA review) [22] and they're working on reimbursement strategies (noting that existing insurance codes for neurostimulators – from pain management – could potentially cover these SCI applications [31]). In summary, Onward is arguably the closest to broad clinical deployment, with **ARC-EX poised to hit the market by 2023–2024** and **ARC-IM in large trials**. If those trials succeed, the next few years could see the first *FDA-approved spinal stimulation therapy specifically for SCI*.

NeuroRestore (EPFL/CHUV, Lausanne)

Who they are: *NeuroRestore* is a Swiss research consortium and center focused on neuroregeneration and neuromodulation, with a strong emphasis on spinal cord stimulation for paralysis. It's essentially an academic program – a joint venture between École Polytechnique Fédérale de Lausanne (**EPFL**), University of Lausanne Hospital (**CHUV**), and University of Lausanne – with philanthropic support. NeuroRestore is not a company but rather a research powerhouse that partners with industry (like Onward) to translate its findings. The center is co-directed by neuroscientist **Prof. Grégoire Courtine** (EPFL) and neurosurgeon **Dr. Jocelyne Bloch** (CHUV). They are based in Lausanne, Switzerland. NeuroRestore was established in the late 2010s (building on prior initiatives like the Defitech Center for Interventional Neurotherapies) to bring together scientists, engineers, and clinicians under one roof to restore neurological function after paralysis.

Background & origins: NeuroRestore emerged from the groundbreaking work of Courtine's lab over the past 15+ years. Courtine began by demonstrating spinal stimulation restoring walking in paralyzed rats (around 2009–2012). In 2014, he and Bloch tested an early epidural stimulator in a partially paralyzed man (achieving stepping on a treadmill). These successes attracted major funding (from sources like the Defitech Foundation, Wings for Life, etc.) to create a dedicated center. NeuroRestore officially launched around 2018. It combines EPFL's engineering and neuroscience expertise with CHUV's clinical setting – meaning they can go from animal models to human trials within one integrated framework. The partnership with Onward Medical is natural: Onward licenses some of the tech and coordinates on trials, while NeuroRestore focuses on fundamental discovery and early-phase clinical studies in Switzerland.

Key people: Grégoire Courtine, PhD – co-director of NeuroRestore – is one of the most influential figures in SCI research today. He leads the scientific strategy, having a background in neuroscience and biomechanics. **Dr. Jocelyne Bloch** – the other co-director – is a neurosurgeon who performs the stimulator implant surgeries and brings clinical insight. Other notable team members include **Prof. Silvestro Micera** (neuroengineer working on interfaces), **Prof. Stéphanie Lacour** (materials scientist developing flexible electrodes), and neuroscientists like **Jordan Squair** and **Luis Barbera**. The center also collaborates with international experts (e.g., **Prof. Martin Schwab** at Zurich on regenerative approaches, **Prof. Aaron Phillips** from Canada for autonomic research [15]). NeuroRestore's work is very multidisciplinary – combining robotics (for rehab training devices), imaging, molecular biology (they even do research on regenerating nerves with gene therapy), and of course neuromodulation.

Past work: NeuroRestore (and its preceding projects) has an impressive list of *firsts* and high-impact studies:
- In **2018**, they published a study where **3 men with chronic complete paralysis (no voluntary leg movement)** were implanted with epidural stimulators and, after weeks of intensive training, *all three regained the ability to walk* with assistance (e.g., using walkers or crutches) [23] [32] . This was a watershed moment reported in *Nature* – the world saw video of these participants taking steps again. The stimulation used precise spatiotemporal stimulation programs (activating specific electrode contacts in sync with intended movements), essentially mimicking how the spinal cord normally activates muscles [24] . This was big news because these were chronic injuries (years post-injury), which previously were thought irreversible. It showed the combination of SCS and rehab can enable dormant circuits to resume function. - In **2022**, NeuroRestore scientists identified a specific type of neuron in the lumbar spinal cord that appears crucial for enabling recovery with stimulation – dubbed "SCvsx2::Hoxa10 neurons," a type of interneuron that was remodelled by stimulation training (published in *Nature*, Nov 2022). Understanding this helps target future therapies and justified why epidural stim can have lasting effects (it triggers plasticity in these neurons). - The team also achieved restoration of **trunk and balance control**. In 2021, they showed that targeting abdominal and back muscle innervation with

selective stimulation allowed people with SCI to improve their core stability and sit, stand, and even perform limited walking with better balance. Regaining core strength is crucial for activities like sitting without support or improved posture. - On the autonomic front, as part of a collaboration with Calgary, they demonstrated that epidural stimulation at T6-L1 can mitigate **autonomic dysreflexia** (AD) – the Nature 2021 study mapped the network causing AD and showed stimulation can "competition" with it to prevent dangerous blood pressure spikes [33]. This laid groundwork for the blood pressure implant described earlier. - Another intriguing line of work: **deep brain stimulation**. In late 2024, NeuroRestore reported that stimulating a region deep in the brain (the lateral hypothalamus) *improved walking in two people* with incomplete SCI who had plateaud in recovery [34] [35]. These patients, when their hypothalamic electrodes were activated during rehab training, suddenly experienced an "urge to walk" and improved gait and even stair-climbing ability [36]. This was a small pilot (2 patients) but demonstrated that the *brain's locomotor centers* can be harnessed – essentially complementing the spinal stimulation from above. It underscores NeuroRestore's comprehensive approach: they're not just stimulating the cord, but exploring **brain stimulation and brain-spine bridging** too. (We'll revisit the brain stimulation aspect in Section 3.3, but it's worth noting here that NeuroRestore is behind that as well, showing the interplay of brain and spine interventions.)

Current work: NeuroRestore continues to run and expand clinical trials in Switzerland. Currently:
- They have a program called **STIMO-2**, a follow-up trial to further refine epidural stimulation protocols for walking, with a larger cohort. They are also looking at *earlier intervention* – possibly implanting stimulators in subacute patients (months after injury rather than years) to see if that yields better outcomes (since the nervous system might be more primed to recover early on).
- **Autonomic projects:** One ongoing trial implants stimulators in people with high SCI specifically to restore blood pressure (the work that led to the Nature Medicine 2022 paper). The results so far are so promising (14 of 14 patients helped) that it's moving to the aforementioned multi-center pivotal stage with Onward [20]. NeuroRestore's lab is also investigating stimulation for other autonomic functions such as bladder control – e.g., whether spinal stimulation can improve bladder storage and emptying (some earlier case reports from other groups hint at improved bladder function as a side effect of SCS).
- **Upper limb:** While much of Lausanne's early focus was on lower limbs, they have now also turned attention to *upper-limb paralysis*. In collaboration with .NeuroRestore, Onward conducted the Up-LIFT trial for hand function (though most sites were outside Switzerland, NeuroRestore contributed know-how and some Swiss participants). After the non-invasive success, they might consider implanted approaches for hand/arm as well.
- **Brain-spine interface:** As described, NeuroRestore, in partnership with CEA in France, achieved the first **wireless brain-controlled spinal stimulation** in a human (Gert-Jan Oskam) [23] [32]. Currently, that is just one patient, but ongoing efforts aim to include more participants to see if the system can be generalized. They use an implant called WIMAGINE in the brain to capture motor intentions and an epidural stimulator in the spine, connected via external computers running AI algorithms [24] [37]. It's cutting-edge research combining BCIs and SCS (truly merging Section 1 and Section 5 of this report). The fact that Gert-Jan's neurological function *improved over time even with the bridge off* (he regained some voluntary movement due to rehab with the bridge) [38] is a key finding – it suggests that this digital bridge not only substitutes for lost connections but helps regrow or reroute them. NeuroRestore is likely to push this technology further, and as noted, they have support to commercialize it with Onward [25].
- **Robotics + stimulation:** They are testing robotic gait trainers and exoskeletons combined with stimulation, to automate and optimize rehabilitation. A March 2025 press release announced that combining rehab robots (for weight support and leg guidance) with SCS enabled faster and more complete recovery in paralyzed patients [39]. This speaks to an integrated rehab approach – technology isn't used in isolation but as part of a regimen.

Major milestones & results: In sum, NeuroRestore's major outcomes include: enabling multiple people with paraplegia to walk with assistance [23]; enabling a man with tetraplegia to walk via a brain-spine interface [23] [32]; identifying fundamental neuronal targets for therapy; restoring blood pressure stability in SCI [17] [18]; and even using DBS to boost recovery [36]. They have produced at least *three papers in Nature or Science in the span of 2018–2023*, reflecting how influential their work is. One participant famously said after years of being wheelchair-bound, *"I can stand at a bar and have a beer with my friends"*, which he described as a simple yet profound pleasure regained [40]. Still, NeuroRestore is careful to point out limitations: these are small cohorts, many individuals still need assistive devices or cannot take stimulation systems home for daily use yet (implants in trials are often externalized or not user-controlled). It's not a cure, but a significant functional improvement.

Future plans for SCI: NeuroRestore's mission is *to translate neurotechnology innovations to patients*. They indicate that next steps are larger clinical studies and partnering for widespread implementation. For example, Courtine has said the goal is to **"move toward widespread clinical adoption"** and they are preparing, with Onward, a multi-center trial across the US, Canada, Europe for the blood pressure device as mentioned [20]. They envision similar multi-center pivotal trials for walking in the future (likely once device improvements are in place). Another future direction is *personalized stimulation*: developing algorithms (possibly AI-driven) that optimize stimulation settings for each individual's unique injury and anatomy – a concept already in progress. Also, as hinted in their statements [41], they plan to extend the brain-spine interface idea to **arm and hand function** and even stroke rehab. This means a person with quadriplegia might get a double implant – one reading brain signals for arm movement, and an epidural stim or FES to activate arm and hand muscles. The timeline for such a BCI-spinal system is longer-term (perhaps later 2020s), but the pieces are falling into place. NeuroRestore will continue blending biological approaches (they also research neuroregenerative therapies like nerve grafts and gene therapy in parallel) with neuromodulation. In a "hybrid future", one could imagine someone gets a stimulator to restore function and also a regenerative therapy to heal the cord – NeuroRestore is one of the few groups tackling both angles.

Overall, NeuroRestore provides the **scientific engine** behind many advances, and through partnerships (with Onward for devices, with clinicians worldwide), they aim to ensure these advances don't remain confined to a lab. Courtine often frames it this way: *20 years ago, no one would have believed a man with chronic SCI could walk again; now it's been shown – our job is to turn this from science to a treatment available for all who need it.* They are realistic that it will take time and global collaboration, but clearly momentum is on their side.

SpineX

Who they are: SpineX Inc. is a startup company based in Los Angeles, California, developing **non-invasive spinal cord neuromodulation** devices for people with SCI and other neurological conditions. It's a **spin-off from UCLA** and the broader "LA neuromodulation ecosystem" that Dr. Reggie Edgerton fostered. SpineX was founded around 2017 by a team including **Dr. Parag Gad** (a biomedical engineer and former student of Edgerton) and Dr. Edgerton himself. It is privately held and has been conducting clinical trials on its devices. Unlike Onward (which has both implantable and external platforms), SpineX is focusing on *external transcutaneous stimulation* as a therapy, often paired with activity-based rehabilitation. Their core technology is embodied in devices like "SCONE™" and "SCiP™".

Background & origins: As noted, SpineX's origin traces to **Reggie Edgerton's lab at UCLA**, which has been a cradle for spinal stimulation discoveries since the 1970s [42] [43]. Dr. Edgerton demonstrated in animals the concept of the spinal cord's central pattern generator and how stimulation could activate it. By the 2010s, Edgerton and colleagues were also showing that **transcutaneous** (surface) stimulation could have many of the benefits of epidural implants. Edgerton chose not to join Onward (after NRT merged with GTX); instead, he and **Parag Gad** struck out on their own to form SpineX around 2017 [44]. Essentially, SpineX can be seen as a *rival* or alternative approach to Onward's external stim, with roots in the same foundational science. They gathered a team of engineers and clinicians in LA and received grants (including NIH funding) to develop their device. SpineX has emphasized *autonomic functions* (bladder, bowel, sexual function) as initial targets, which set it apart from others initially focused on walking.

Key people:
- **Dr. Reggie Edgerton** – co-founder and Chief Scientific Officer. Now in his 80s, Edgerton is still actively guiding the science. His 50-year legacy is literally the spine of the company (SpineX's website even narrates Edgerton's story and how it led to the company's formation [42] [43]).
- **Dr. Parag Gad** – co-founder (previously Edgerton's mentee), he has served in roles like Chief Technology Officer. Gad has published extensively on spinal stimulation and spearheaded translating lab findings into a commercial device.
- **CEO:** SpineX's CEO as of recent years is **Jorge Tacla** (according to press releases), bringing a business side. But the technical and clinical leadership includes folks like **Dr. Daniel Lu**, a UCLA neurosurgeon who has collaborated on spinal neuromodulation research, and **Enrique Vergara** (lead engineer).
- The team includes neurologists, urologists, and rehab specialists as advisors because of their focus on bladder and other functions.

Past work: SpineX started by testing their non-invasive stimulation on specific problems that matter to SCI patients:
- One of their earliest focuses was **neurogenic bladder dysfunction**. They developed a therapy they call **SCONE™ (Spinal Cord Neuromodulator)** for treating urinary incontinence and bladder issues in people with SCI and other disorders. A pilot study showed that transcutaneous stimulation over the lower spine could improve bladder emptying and reduce overactive bladder symptoms [45]. For example, some participants were able to better sense bladder fullness and had fewer accidents. This was a significant finding since bladder control greatly affects quality of life and until now mainly had pharmaceutical or catheterization solutions.
- They also targeted **children with cerebral palsy (CP)** and other pediatric motor disorders. In a notable trial, SpineX applied transcutaneous stimulation in children with CP and reported improvements in motor function (some children gained better trunk control and mobility). This broadened their scope beyond SCI and caught media attention because it's a non-invasive, low-risk intervention for kids who have limited options.
- In adult SCI, beyond bladder, SpineX has been investigating **spasticity reduction** and **motor recovery**. For instance, they have a program called "SCiP™" which presumably stands for spinal cord innovative stimulation for paralysis (or similar). Early case studies by the team (even before the formal company) showed that transcutaneous stimulation could enable voluntary leg movements in people with chronic paralysis if done in conjunction with rehab training – akin to what epidural stim did but with surface pads.

Importantly, in 2022 it was noted that SpineX was in the middle of a **large clinical trial** of its transcutaneous device (SCONE) focusing on bladder outcomes, enrolling around 130 patients at multiple centers [44]. This indicates the company moved into later-stage testing, at least for the bladder indication. They also received an FDA Breakthrough Device designation for an indication related to incontinence, which helps expedite development.

Current work: SpineX's development pipeline includes:
- **SCONE™ device**: a multi-use external stimulator. The SCONE device uses adhesive electrode patches placed on the lower back (for lower-body targets) or neck (for upper-body targets) and delivers specific stimulation waveforms. It's paired with rehab exercises. The main trial with SCONE is for **urinary**

function in SCI. As of mid-2020s, they were recruiting SCI participants who have neurogenic bladder to test if SCONE can reduce the need for catheterization by improving voiding efficiency. The trial is large (130 patients, 4 sites) (44), signaling confidence in its potential. If successful, SCONE could become the first non-surgical treatment that restores some bladder control. Early results reported by SpineX suggest *decreased detrusor overactivity and improved continence* across different conditions (45) – basically it can calm an overactive bladder and help in storage and emptying (45).
- **SCiP™**: This is another product in development, likely tailored for *motor rehabilitation*. It might be an evolution of SCONE with different software for limb movement recovery. (The website doesn't detail SCiP, but it implies a platform for improving walking or hand function in SCI patients).
- **Clinical trials in mobility**: SpineX has been collaborating with research hospitals (like UCLA, UC San Diego, Rancho Los Amigos National Rehab Center) on studies where participants with paralysis undergo transcutaneous stimulation plus physical training, to see improvements in voluntary movement. For instance, a recent study reported that non-invasive stimulation enabled some individuals with cervical SCI to perform hand and arm movements they couldn't before (like opening a hand or lifting an arm), with training. SpineX tech was used in a published experiment that allowed *paralyzed people to open doorknobs and open bottles for the first time in years* using transcutaneous spinal stimulation (46).
- **Autonomic and other functions**: The company's mantra includes improving *bowel and sexual function* as well. It's known that the sacral circuits for bowel and sexual reflexes could potentially be modulated by similar non-invasive stim. While less publicized, these are likely areas they are exploring, since any neuromodulation that improves bladder often affects those systems too (due to anatomical proximity).
- **Regulatory progress**: SpineX will likely seek FDA approval or clearance for the SCONE device. Possibly first as a therapy for neurogenic bladder in SCI (since that's a high-need indication). They might also pursue approvals for spasticity treatment or mobility enhancement as an "aid to rehabilitation". In 2023, they announced an FDA Breakthrough Device designation for SCONE in treating cerebral palsy, interestingly – indicating the FDA sees promise in a broad neuro population.

One noteworthy aspect: SpineX's approach is generally *lower cost and less invasive* than implants. Their vision is something a rehab center or even a home user could adopt easily (a portable stim unit with stick-on pads). It might not achieve the same magnitude of effect as an epidural implant in every case, but if it can achieve, say, 50% of the benefit with 0% of the surgery, it's attractive, especially in resource-limited settings.

Major milestones & results:
SpineX is newer than the likes of Onward, but some milestones include:
- The company frequently cites that its tech has been used in **over 100 patients** across various studies (including SCI, stroke, CP). This cumulative experience helps fine-tune protocols.
- **Bladder study successes:** In a scientific publication, SpineX-affiliated researchers showed **significant improvements in continence** with transcutaneous stimulation (TESCoN) in patients with SCI and other neurological diseases (45). This was one of the first demonstrations that an external stim could directly impact bladder function in humans. The results included decreased involuntary bladder contractions and improved ability to void, which are huge for independence (less reliance on catheters).
- **Pediatric milestone:** The use of spinal stimulation in **children with cerebral palsy** was a novel extension. After a treatment course, some children showed better motor function (one press release described a child going from needing support to taking steps with a walker after treatment). This has given hope that neuromodulation could aid brain injuries and developing nervous systems as well. It also indicates safety in younger populations.
- **SCI mobility:** While much of the epidural work gets the spotlight, SpineX's non-invasive method also has case reports of enabling stepping and voluntary control. A UCLA-led study (noted on UCLA News 2019) showed transcutaneous stimulation plus intensive rehab allowed several paraplegic participants to regain voluntary leg movement (like moving legs on command) and improved walking with harness support. Those results were preliminary but mirrored the epidural outcomes in a less invasive way. One

participant in a SpineX-related study described being able to perform daily activities like transferring more easily due to improved trunk control from stimulation.

It's important to manage expectations: transcutaneous stimulation often requires **high intensity currents** (to penetrate to the spinal cord) and can be uncomfortable (SpineX claims their waveform is "painless" by using a particular frequency pattern [47], which if true, is a big advantage). Also, the results can vary – some people respond strongly, others mildly. So, part of SpineX's ongoing work is understanding how to customize and optimize stimulation for each user (maybe adaptively increase as the person does a task).

Future plans for SCI: SpineX aims to bring **at-home neuromodulation therapy** to patients. Dr. Gad has mentioned envisioning a future where a person can put on a stimulation belt or garment daily and get on with therapies or activities that improve their function. Concretely, the company likely plans to seek FDA approval for **SCONE as a therapeutic device for neurogenic bladder** in the near term, given their large trial. If they secure that, SCI patients (and those with similar bladder issues from other causes) could get a prescribed device and use it regularly to reduce catheter use or improve continence. Next, they will pursue indications for *mobility and function*, possibly positioning their stim device as a **rehabilitation aid** to improve motor outcomes. For example, they might market it to rehab clinics as a tool to incorporate in therapy sessions for improving walking or hand use. If efficacy is clearly demonstrated, it could become a **standard adjunct to physical therapy** for SCI.

SpineX is also expanding into other neurological markets (CP, stroke, multiple sclerosis etc.), which helps the business case (SCI alone is a relatively small market, a common challenge noted [48]). But SCI remains a core focus and passion for the founders. They have a **philosophy of accessibility** – since it's non-surgical, their solution could reach many who cannot travel to a specialized surgical center. It could also be applied earlier post-injury (since there's no risk of surgery in a still-recovering patient). We should note that **competitors in transcutaneous SCS** are on the horizon too (e.g. Aneuvo, see next, and even large medtech might jump in), so SpineX's plan is likely to be *first to market* with a proven device.

In summary, SpineX represents the *non-invasive wing* of the SCI stimulation movement. If Onward is placing big bets on implants, SpineX bets you can achieve a lot without implants. Ultimately, both may have roles – perhaps someone starts non-invasive and if that's not enough, progresses to an implant. SpineX's near-term deliverables (like a bladder neurostimulator) could fill an unmet need fairly soon, bringing tangible improvements in quality of life (imagine fewer daily catheterizations, or none at all – that's huge). And down the line, SpineX will likely also contribute to combined systems (they could integrate their external stim with other tech like transcranial stimulators, or even BCIs, to coordinate brain and cord activation non-invasively).

Aneuvo

Who they are: Aneuvo is a neurotechnology startup developing a **transcutaneous spinal stimulation system** called **ExaStim®.** The company is based in Los Angeles, California (forming part of the same "UCLA-Caltech neuromodulation cluster" as SpineX). Aneuvo was originally founded as "Niche Biomedical" in 2016 by engineers **Dr. Wentai Liu** and **Dr. Yi-Kai Lo**, and later rebranded to Aneuvo in 2021 [49]. It's a privately held company. Aneuvo's mission is to help people with paralysis regain function through a *wearable, easy-to-use stimulation device*. In essence, Aneuvo is a direct competitor in the non-invasive SCS space (competing with SpineX and also overlapping with Onward's external device efforts). The company's name "Aneuvo" likely alludes to "neuro" and "innovation/anew."

Background & origins: The founders have deep expertise in bioelectronics. **Dr. Wentai Liu** is a distinguished professor of bioengineering at UCLA (formerly at UC Santa Cruz) known for implantable devices – he co-invented the "bionic eye" (Second Sight's retinal prosthesis). He joined the SCI neuromod field when Edgerton recruited him in 2013 to help design better epidural electrodes for NRT (50). **Yi-Kai Lo, PhD** was one of Dr. Liu's postdocs; together they worked on advanced stimulators. When NRT pivoted and eventually merged into Onward, Liu and Lo decided to pursue their own path, focusing on a **non-invasive stimulator** with sophisticated capabilities (49). This became the ExaStim system. Aneuvo set out to conduct a large trial with ExaStim soon after rebranding: in 2021 they announced a multicenter trial for **upper extremity function**, aiming to enroll 150 patients at 10 sites (49). Such ambition early on was notable and signaled they had confidence and possibly NIH or other support. The company also received FDA Breakthrough Device designation and a CE Mark in Europe for ExaStim, indicating regulators see potential (51).

Key people:
- **Wentai Liu, PhD** – Co-founder and likely Chief Scientific Advisor. A veteran in bioelectronics, he provides the engineering vision.
- **Yi-Kai Lo, PhD** – Co-founder and CEO/CTO (often the face of the company in talks). He's an expert in stimulation waveform engineering and in creating user-friendly interfaces.
- **Leadership/Advisors:** Aneuvo's team includes clinical advisors like **Dr. Thomas Chau** (a rehab expert) and others bridging engineering and medicine. Since they sponsored a U2FP symposium and have interacted with the community, they appear to have a small but passionate team. The company's Chief Growth or medical officers are not publicly famous names; the technology credibility really stems from Liu's and Lo's background.
- Aneuvo has also engaged with investors and incubators (for example, they had connections with the UCLA innovation fund and some VC backing after showing early results).

Past work: The main output of Aneuvo so far has been the **ExaStim® system development and early testing**. ExaStim is described as a *16-electrode* transcutaneous stimulation pad and a controlling unit with a touchscreen interface (52) (53). Key points from early work:
- ExaStim was designed to be *flexible and adherent to the skin*, moving with the body (53), and to have **multiple independent channels** to stimulate different muscle groups in sequence. The company touts "30+ preset movement sequences" in its software and the ability to stimulate up to 8 muscle groups at once with its 8-channel stimulator (54). This suggests a high degree of control, e.g., they can program a coordinated reaching motion by sequentially activating shoulder, then elbow, then hand muscles – effectively pre-programmed functional movements.
- **Safety/comfort:** They emphasize ExaStim is non-invasive and *avoids surgical risks*. They also claim it's comfortable ("therapy without the risks and complications of surgery" and their waveform is tolerable) (55).
- **Upper-limb focus:** Their initial therapy is aimed at improving voluntary *arm and hand function* in patients with upper-limb paralysis due to cervical SCI or stroke (56). They position it as retraining the brain and body via repetitive stimulation during specific tasks, leveraging neuroplasticity (57) (58). In other words, the stimulation helps reinforce the attempted movement, and with repetition, the brain relearns to send signals and the spinal circuits reorganize. They often mention improvements seen after ~20 hours of therapy (59) – so roughly a few weeks of sessions – where patients started regaining voluntary control.
- ExaStim was tested in a multicenter RCT (the one with 150 patients mentioned). Some preliminary outcomes have been hinted: e.g., *case studies of quadriplegic patients who after a month of ExaStim therapy could do things like pick up a drink and bring it to their mouth unaided for the first time in years* (60) (61). The Aneuvo website provides such testimonials: one C5/C6 injury patient reported being able to drink without a straw after 1 month of sessions (60); a mother of a high injury son said in 4 weeks he could hold and pour a drink by himself (61). These anecdotes, while not peer-reviewed evidence, echo

what small studies have found: FES/spinal stimulation can yield *meaningful functional gains in upper limbs*.
- ExaStim also got a CE Mark in Europe (which suggests it met basic safety and performance for commercial use in EU) (51) , and Breakthrough Device status from FDA (51) . So they have regulatory traction.

Additionally, Lo and Liu likely leveraged some of their prior research – for instance, Yi-Kai Lo published on an earlier version of multi-channel transcutaneous stim and demonstrated its effects in a lab setting. They also participated in conferences (as noted, Lo spoke at U2FP 2021 detailing their strategy (62)).

Current work: Aneuvo's focus as of 2025 is on **bringing ExaStim to market and expanding its uses**. Key components:
- **Upper limb therapy rollout:** In Canada, ExaStim is *approved for both upper and lower limb therapy* (63) , and in the US it's cleared (by FDA) for upper limb in stroke and SCI (64) . This implies they achieved a regulatory clearance (likely as a Class II device) based on their trial evidence. So currently, clinics in Canada can use ExaStim for arm/hand and possibly leg training. In the U.S., it can be used for arm/hand rehab in stroke and SCI (C3–T1 level injuries) (65) (66) . This is a significant development – it means *rehab centers could buy an ExaStim and start offering the therapy*, presumably under clinician guidance. Aneuvo likely provides training certification for therapists (as indicated: only trained professionals can administer it (67)). - **Lower limb therapy:** Having gotten Health Canada approval for lower limb, Aneuvo is now promoting its use for improving walking or leg function (likely in incomplete paraplegia or perhaps stroke gait). This might involve sequences for stepping, knee control, etc. While less data has been shown publicly on lower limb, their tech should in principle handle it (the pad could be placed over lumbar region to stimulate leg nerves). Perhaps their big U.S. trial was only arms, so they might need more data for legs in U.S. But since Canada approved it, they must have shown some evidence there.
- **Home and clinic use:** Aneuvo emphasizes the portability and ease of ExaStim – it's tablet-controlled, battery-powered, and "moves with you" from clinic to home (68) . They highlight that therapy can continue at home, which is important for long-term gains. The device is described as lightweight and even usable while the person performs real-world tasks. Their vision is likely that a patient can eventually have an ExaStim at home (with periodic check-ins or tele-supervision by therapists). This addresses a limitation of many therapies that only happen in clinic.
- **Ongoing studies:** Even with commercial steps, they probably continue to study new populations (for example, could ExaStim help *sensory recovery*? They did mention improved sensation in some cases). They might also explore pairing ExaStim with **brain stimulation or BCI** for even better control – given Wentai Liu's background in brain implants, perhaps in the future they integrate non-invasive EEG or other signals. But their current messaging is mostly on their stand-alone therapy.
- **Manufacturing and scaling:** As a small company, a big current task is scaling up manufacturing to supply devices, and training clinicians to use them effectively. They boast user-friendly interfaces (touchscreen, presets) to lower the adoption barrier (69) .

Major milestones & results:
Aneuovo's milestones include: - Achieving a **CE Mark (EU)** and likely an FDA 510(k) clearance for ExaStim (making it one of the first dedicated transcutaneous SCI neurostimulation devices cleared for therapy).
- Completing (or at least well advancing) a large RCT in SCI for upper-limb function. If published, that would provide high-quality evidence. A hint from a Frontiers in Neurology 2022 paper suggests *40 sessions of MyndMove (a similar FES therapy) were as effective as intensive conventional therapy* (70) . We suspect ExaStim's RCT might show at least comparable if not superior outcomes to standard rehab. If it shows superiority, that's huge; if it's equal, it still offers another tool.
- **Breakthrough moments in patients:** as per their site, patients using ExaStim have reported regaining abilities like feeding themselves, holding objects, and improved sensation (60) (61) . One media story referenced (e.g., "Massachusetts skier faces uphill climb…") presumably covered a patient using

ExaStim in rehab and regaining some movement [71] [72]. These human stories help validate the tech's impact.
- Another milestone: **external validation** – Aneuvo was chosen by TIME magazine as one of "2025 Best Inventions" for its Axon headset (which might be a confusion with Cognixion's Axon? Or it could be misreferencing ExaStim's tech... Actually, the search result [9] suggests Cognixion's Axon-R got Time's list. Perhaps Aneuvo has not such pop press, but being invited to major SCI conferences and partnering with big rehab hospitals (they mention being featured by leading networks and podcasts [73]) shows increasing recognition.

Future plans for SCI: Aneuvo's future plans likely include:
- **Commercial deployment**: Getting ExaStim into *rehab networks* (especially SCI Model System centers, VA hospitals, etc.). They'll gather post-market data on how it improves outcomes when integrated into standard care. If clinics and patients find it beneficial and not too difficult to use, it could become a routine part of SCI rehab (much like FES bikes are now common in many rehab centers for conditioning).
- **Broadening indications**: They will likely seek expanded FDA clearances – e.g., to explicitly market for *walking improvement in SCI*, for *children with SCI or CP*, etc. Also, stroke and MS markets are on their radar. The more indications, the larger their impact and revenue, which can fund further SCI-specific innovation.
- **Next-gen tech**: Aneuvo might develop a fully wearable version (perhaps an integrated garment or something even more user-friendly) in later generations. They could also implement *closed-loop features* (sensors that detect muscle activation or movement and adjust stimulation).
- **Comparative studies**: In the field, inevitably someone will compare Onward's ARC-EX vs Aneuvo's ExaStim vs SpineX's device when all are available. Aneuvo will want to demonstrate that their solution has either better outcomes or is easier/faster. They highlight some differentiators: e.g., a **16-electrode flexible pad** (others might have fewer channels), an **intuitive tablet app** (for therapists to program multi-joint movements), and **portability**. If these translate to more effective or more versatile therapy, that will be a selling point.
- **Vision**: Aneuvo sees FES/spinal stimulation not as a passive thing but as an *active training that leads to lasting recovery* [57] [58]. They lean into the neuroplasticity angle, hoping that after enough sessions, patients won't need to rely on stimulation constantly – they'll have re-established some voluntary control. This is somewhat aspirational; likely many will still benefit from continued use, but even partial recovery is valuable. The company's communications also mention *"creating a healthier, more equitable world for people with disabilities"* [74] – implying a commitment to accessibility. They might aim to make the device *affordable* or push for insurance coverage so that many can access it, not just a few.

In short, Aneuvo is one of the key players ensuring that **non-invasive neuromodulation becomes practical for SCI rehab**. Together with SpineX (and to some extent Onward's ARC-EX), they form a cohort of companies translating decades of FES knowledge into modern smart stimulation therapies. Their success could mean that within 5-10 years, anyone with a C5 injury undergoing rehab will routinely get a transcutaneous stim therapy course to maximize their hand function – something that was not standard care in the past. That is a concrete near-term hope for the SCI community.

Louisville and Kessler Foundation Programs

(*Note: These are not companies, but major academic/clinical programs that have driven SCS research and are now pioneering new trials.*)

University of Louisville / Kentucky Spinal Cord Injury Research Center: This is the program led by **Dr. Susan Harkema** at the University of Louisville in Kentucky, often simply referred to as "Louisville" in

SCI circles. It’s historically significant as the site of the **first human epidural stimulation trials** and continues to be a world-leading research hub.

- **Origins and key people:** Dr. Harkema, a neuroscientist and rehab specialist, trained under Reggie Edgerton at UCLA and then moved to Louisville. In 2009, her team implanted a Medtronic epidural stimulator (originally designed for pain) in a young man (Rob Summers) who was completely paralyzed. In 2011, they reported he could stand and regain some voluntary toe movement with stimulation – *the first documented human epidural stimulation success* [3] . This opened the floodgates. Harkema and colleagues (including **Dr. Claudia Angeli** and **Dr. Enrico Rejc**) went on to implant and train more patients. They published a landmark 2018 paper in *New England Journal of Medicine* with four participants (all chronic cervical or thoracic SCI) who with epidural stimulation and intensive rehab, recovered the ability to stand and even step on a treadmill, and two of them could make steps over ground with a walker and assistance. This demonstrated the repeatability of the result – not a one-off. Key figures: besides Harkema, **Dr. Claudia Angeli** was a leading scientist at Louisville’s program (she has since also taken a role at Kessler Foundation, see below, but remains closely collaborating). **Dr. Yury Gerasimenko** (a Russian neuroscientist) also worked with the Louisville team, contributing to transcutaneous stimulation methods.

- **Major accomplishments:** Louisville’s program not only showed motor recovery, but also documented **secondary benefits** of epidural stimulation: improved blood pressure control, better temperature regulation, improved sexual function, and even some bowel/bladder improvements in participants (often reported anecdotally in studies). For example, one participant was able to regulate his blood pressure better and avoid blacking out upon sitting up after the implant, and another female participant regained some bladder sensation and voluntary voiding ability. These multifaceted gains underscored that neuromodulation could address *whole-body issues* of SCI, not just movement. Louisville also emphasized the importance of **activity-based training** combined with stim – participants underwent daily locomotor training and task-specific rehab for months. Harkema’s approach was that stimulation opens a window of opportunity, but training drives actual functional gains.

- **Current work:** The Louisville group continues to innovate. They have ongoing trials (funded by NIH, the *Craig H. Neilsen Foundation*, etc.) looking at:

- Epidural stimulation in **acute or sub-acute SCI** (they’re exploring if implanting within months of injury yields better outcomes, under a study called “Big Idea”).
- **Optimizing stimulation** – they are experimenting with spatiotemporal patterns (like the ones Courtine’s team uses) versus simple continuous stimulation to see what gives the best voluntary control.
- **Epidural stimulation for cardiovascular health** – some studies examine stimulation’s effect on heart and vascular function (important because cardiovascular disease is a leading killer in chronic SCI).
- **Expanding participant demographics** – including people with **motor complete injuries (AIS A/B)** who were long told they had zero chance of regaining movement. Many of Louisville’s participants were motor complete and yet regained voluntary movements with stimulation, fundamentally changing prognosis for AIS A folks.

- Additionally, **neurophysiology studies**: By recording muscle EMG and using stim as a probe, they learn how residual connections respond. This yields insight into the mechanism (like seeing that even “clinically complete” injuries often have some dormant connections that stim helps unmask). The Louisville team is somewhat technology-agnostic: they use commercial stimulators (from Medtronic usually) and heavily focus on the rehab side. They haven't commercialized a device themselves, instead their findings fed into NRT and thus Onward. But they remain a crucial site for **ongoing clinical evidence**. In fact, Louisville is often a participating site in multi-center trials (for example, they collaborated with Mayo Clinic and others in some of the 2018–2019 implant studies). They also host conferences (in 2022, Harkema hosted a major SCI neuromodulation symposium [75] to share global knowledge).

- **Future plans:** Louisville's program will likely remain at the forefront of *refining epidural stimulation therapy*. They are working on predictors of who will respond (e.g., studying if certain spared fibers on MRI correlate with success). They are also part of new projects like an NIH BRAIN initiative grant (with Kessler) to explore stimulation effects on bladder & locomotion in sub-acute SCI [76]. Harkema has expressed the goal of moving toward FDA approval as well, though she's a researcher, not a company – hence partnerships with companies (e.g., she was an advisor to NRT/Onward and she's collaborating with Medtronic and others to push a stimulators specifically labeled for SCI use). The **end vision** from Louisville's perspective is that rehab centers around the country will offer epidural stimulation as a therapeutic option, and insurance would cover it, similar to how some centers now offer it in research. They are training the next generation of researchers and clinicians on these techniques, ensuring the knowledge spreads.

Kessler Foundation's Center for Spinal Stimulation (New Jersey): The **Kessler Foundation** (based in West Orange, NJ) is a nonprofit research institution affiliated with Kessler Institute of Rehabilitation. In 2019, Kessler Foundation established the **"Tim and Caroline Reynolds Center for Spinal Stimulation"** with a major philanthropic donation, explicitly to advance epidural and transcutaneous stimulation research. This effectively created an East Coast hub similar to Louisville. They recruited top talent and launched new studies, complementing what Louisville and others have done.

- **Key people and origins:** Kessler brought on **Dr. Gail Forrest, PhD** to direct the Center – she had been involved in SCI locomotor training and stimulation research for years at Kessler. Importantly, they also hired **Dr. Claudia Angeli, PhD** as assistant director [77]. Claudia Angeli came from Louisville (where she was a leading researcher under Harkema and first author on some of the key papers). So Kessler's team merges expertise from Louisville with Kessler's existing rehab research strengths. **Dr. Steven Kirshblum, MD**, a renowned SCI physiatrist (and Kessler's Chief Medical Officer), co-directs the center [78], bridging research and clinical practice. Additionally, neurosurgeon **Dr. Robert Heary** (from Atlantic Health System) is the surgical lead for implants in NJ [79].

- **Major milestones:** In February 2025, Kessler announced the **first ever epidural stimulator implantation in New Jersey** (and likely one of the first in the U.S. outside of Kentucky or Mayo) [80]. They performed the surgery at Overlook Medical Center in NJ, funded by a donor, and combined it with intensive post-surgery rehab at Kessler [80] [81]. This marked a significant expansion of epidural stimulation availability. It's part of an NIH-funded trial (via the BRAIN Initiative) targeting people with SCI <12 months post-injury, to see if stimulation plus training can improve **bladder function and locomotion** in those relatively newly injured [76]. By targeting sub-acute patients, they are investigating whether earlier intervention prevents complications and enhances recovery, possibly tapping into plasticity before chronic phase sets in. Gail Forrest noted this *"underscores the potential of epidural stimulation to change lives"* [82].

Kessler's center also actively researches **transcutaneous stimulation** (they run studies on non-invasive stim for cardiovascular function [83] [84], for example, showing that *lumbosacral transcutaneous stim can improve blood pressure and circulation in SCI* [85]). They examine how stimulation can be combined with

robotic standing devices to improve balance [86], and how stimulation affects **cough and breathing** (some investigators like Dr. Glenn Wylie at Kessler have looked at phrenic stim or respiratory benefits).

- **Current work:** The Kessler Spinal Stimulation Center is running multiple studies:
- The aforementioned **epidural implant trial for sub-acute SCI** (they plan to implant and train several such patients, focusing on bladder and leg outcomes, with Angeli and Forrest as PIs). This study also monitors outcomes like motor control, cardiovascular and respiratory changes [87].
- **Long-term follow-up**: Kessler is conducting long-term follow-up of individuals who got epidural implants in earlier studies (like those done at Louisville) to see how sustained the benefits are and any long-term issues [88]. This is important for understanding things like how often surgery might need to be redone, or whether people maintain function years later.
- **Transcutaneous trials**: They have studies using **transcutaneous spinal stimulation (scTS)** to improve blood pressure, reduce spasticity, and improve leg function. One Kessler study found that daily transcutaneous stimulation over 5 weeks **improved orthostatic blood pressure stability** significantly in people with SCI [85] – basically an easy, non-drug way to manage a chronic problem. Another study looks at combining transcutaneous stim with exoskeleton walking to see if it enhances outcomes (since exoskeletons alone don't restore function, maybe adding stim could engage the spinal cord more).

- **Robotic postural training + stim**: As referenced in search results, Kessler scientists are investigating if adding stimulation while patients practice standing with a robotic assist can lead to better postural control [89]. The synergy of *neurostimulation + high-tech rehab devices* is a theme.

- **Future plans:** Kessler Foundation intends to be a key site for **pivotal trials** leading to FDA approval of stimulators for SCI. In fact, as more companies (like Onward) start pivotal trials, Kessler is likely to be one of the 20 centers in Onward's upcoming blood pressure trial [20] and possibly mobility trials. By building surgical capability in NJ (with Dr. Heary) and rehab expertise (Forrest, Angeli), they set themselves up as a **Center of Excellence** for neuromodulation. The presence of Angeli is notable: she was integral in developing specialized stimulation programs (she in Louisville helped figure out how to tweak stim settings to evoke stepping etc.). Now at Kessler, she'll apply that to more patients, and crucially, train others. Kessler will also focus on *accessibility and translation*: they don't want this to remain research only. Steven Kirshblum's involvement, as a prominent SCI clinician, suggests they aim to integrate these therapies into clinical practice. Kirshblum stated excitement "to harness the potential of epidural stim… potentially paving the way for improved function and quality of life in the future" [78]. This reflects a mindset of moving it toward standard of care eventually.

Furthermore, Kessler's work could influence **insurance coverage** arguments: as a research foundation, they'll likely publish cost-benefit analyses if stim improves independence (e.g., fewer health complications or caregiving needs could offset device costs).

Scrutiny and Caution: Both Louisville and Kessler (and the wider research community) are very data-driven and cautious about not overpromising. They often highlight that **results vary**: not every person with an implant has walked, some regain less dramatic improvements (like maybe improved trunk stability or just some leg movement). Also, these are not at the stage of *easy outpatient therapy* – epidural stim requires major surgery and months of rehab, and it's currently done only in experimental settings. They also point out the need for *refinements*: e.g., current implants are actually repurposed pain stimulators with limitations (fixed electrode spacing, not ideally covering all necessary spinal segments). Developing **next-gen stimulators tailored to SCI** (with more electrodes, better targeting) is a priority – here they rely on companies like Medtronic or Onward to innovate hardware, while the researchers innovate stimulation protocols. So the message is hopeful but honest: epidural stimulation is very promising and likely to enter clinical practice, but it's not yet an off-the-shelf cure and requires committed participation from patients.

In summary for SCS: Spinal cord stimulation has evolved from a daring experiment to a multi-faceted therapeutic strategy. Organizations like Onward and NeuroRestore are pushing technology and science forward, SpineX and Aneuvo are ensuring non-invasive options, and academic groups at Louisville and Kessler are expanding knowledge and bridging to clinical adoption. Together, they have fostered *real, tangible recovery in functions once thought permanently lost.* People with chronic SCI have stood up, taken steps, moved their hands, and improved vital bodily functions thanks to SCS. In terms of clinical readiness: **external stimulation therapies** (like Onward's ARC-EX and Aneuvo's ExaStim) are **very close or just entering the market**, meaning in the next year or two more patients can access them. **Epidural implants** are likely a few years behind in reaching widespread use – perhaps by the later 2020s if trials are successful and FDA approvals follow – but they're on the horizon. We are looking at a future where **spinal stimulation might become a routine part of SCI rehab**, used in specialized centers to maximize recovery, much like intensive physiotherapy is today.

Verita Neuro (Bangkok) – A Special Case

Verita Neuro is a very different kind of entity among those discussed: it's a **private medical provider/clinic** rather than a research organization or medtech company. Verita Neuro operates internationally (with facilities in **Bangkok, Thailand, and Guadalajara, Mexico**, and plans for expansion) and offers *neuromodulation treatments to patients on a fee-for-service basis*. Notably, Verita Neuro was **"the first facility in the world to offer epidural stimulation for SCI outside of clinical trials."** [90] In other words, they took the research pioneered in academic settings and began providing it as a paid treatment to patients who did not want to wait for formal trials or approvals. This has made Verita both a source of hope for some patients seeking immediate treatment and a subject of controversy in the medical community due to the unproven and for-profit nature of its offerings.

Who they are & origins: Verita Neuro was originally part of a group called **Unique Access Medical (UAM)** in Thailand [91]. UAM, and now Verita, have roots in medical tourism and regenerative medicine. Around **2015**, seeing the emerging results from epidural stimulation research, this group partnered with Thai surgeons to perform the **first epidural stim implant outside a research trial** (Nov 2015) [92] [93]. They essentially *translated the academic procedure into a private treatment*. Verita Neuro as a brand was established later (the company marks 2015 as their start, with a headquarters initially in Singapore for R&D [92]). By April 2016, they opened their own facility in Bangkok where patients could get the surgery and undergo rehab on-site for several weeks [94] [95]. Over the past decade, Verita expanded and claims to have performed **over 300 implantations** to date [96] [97] and to be treating over 200 patients per year as of 2025 [98]. They also introduced complementary treatments (like "LamiSpine" stem cell therapy in 2017) [99] and even a form of *brain stimulation* for some cases. The leadership of Verita Neuro includes entrepreneurs rather than famous scientists. The Chief Growth Officer **Hanna Charles** has been a spokesperson (as per the 10-year reflection piece [100]). The founder/CEO was originally **Julian Andriesz**, a businessman who created the Verita Health group. They employ surgeons in Thailand and Mexico who carry out the procedures and a team of physiotherapists for rehab.

Treatment model: Verita Neuro offers a **"treatment package"** for SCI patients that typically includes: - **Implantation of an epidural spinal cord stimulator** – they use a commercially available device (often a Medtronic or Nevro unit) and place electrodes on the dura at specific spinal segments corresponding to the patient's injury level. The surgical technique is similar to the research trials, though specifics might vary by surgeon. - **Device mapping and programming** – post-surgery, their staff systematically test different stimulation parameters (frequencies, amplitudes, electrode combinations) to find programs that elicit movements or improvements in the patient (e.g., leg extension, toe movement, etc.). They advertise over “116 hours of device mapping and physical therapy” in some patient promotions [101], implying a very intensive regimen. - **Intensive rehabilitation** – patients typically stay for around **30–35 days** after surgery (as mentioned, their Bangkok program started with 35 days of physio built in [94]). Therapy includes locomotor training (weight-supported treadmill, overground walking with trainers), FES cycling, and functional training for upper limbs if needed. Essentially, they combine the stim with activity-based training, similar to the methods used in research – the difference is the patient pays for it as a clinical service. - **Optionally add-ons** – Verita also offers **stem cell injections (LamiSpine)** where they surgically place stem cells at the injury site, and **transcranial magnetic or direct current stimulation** as adjuncts, depending on the package. They brand “dual stimulation” – e.g., **“dual epidural stimulation”** meaning they can implant two stimulators, one in the lumbar region for legs and one in the cervical for hand/arm, to treat quadriplegia [102]. Indeed by 2020 they did the first case of two stimulators in one patient for four-limb paralysis [102]. They also list “Brain Stimulation” as a treatment – possibly referring to transcranial magnetic stimulation or a non-invasive BCI training (not fully clear from their site). - **Aftercare:** Patients return home after the stay, with recommendations to continue therapy. The device remains implanted and can be used via a remote. Some patients have reported continuing improvement months after returning, presumably by doing exercises with the stim on. Verita sometimes provides remote coaching.

The **cost** of this package is high – social media references suggest around **$100,000 USD** for the stim implant and rehab [103], with additional for stem cells etc. They have encouraged patients to do fundraising (as seen in patient interviews on their site) [104]. A number of patients have crowd-funded or received government funds (e.g., Qatar’s government sponsored a citizen to go to Thailand for this [105]).

Evidence cited: Verita Neuro often cites the academic studies (Courtine’s, Harkema’s, etc.) as rationale. They also have published some of their **own data**: In 2021 they presented a “clinical study” of their first 33 patients, claiming all improved motor scores and some gained ability to stand or step [106]. However, this was not a peer-reviewed journal article (likely a white paper or conference poster). They operate in the realm of case series and patient testimonials rather than controlled trials. For instance, their website shares videos of patients who after treatment could move limbs or even take assisted steps. These are powerful stories – e.g., a young man with complete injury moving his legs for the first time after stim, or a woman feeding herself again.

Controversies and scrutiny: The scientific community has raised **concerns** about Verita Neuro because: - The treatments are done *outside of regulatory approval*. (The stimulators are approved for pain, not SCI; in Thailand and Mexico the regulatory environments are different, allowing off-label surgeries with less oversight.) - There’s *no control groups or long-term published outcomes*, so it’s hard to know how effective it truly is across their patient population or if some improvements are due to extensive therapy/placebo. - They charge large sums, which could be seen as **exploiting patients’ hopes**, given that formal proof of efficacy is not established and that patients assume all the risk/cost. - Combining stem cells with stimulation complicates things – if a patient improves, we don’t know which intervention (or synergy) did it, and stem cell procedures carry their own risks. - Some worry it could harm legitimate research – e.g., if a patient has a bad outcome or complication in an unregulated setting, it might create fear or regulatory hurdles that affect research trials.

To Verita’s credit, they report **no serious adverse events** so far (aside from expected surgical recovery). They have now a track record of ~10 years, which suggests basic safety is acceptable (spinal cord stim implants for pain are known to be safe when done properly, and they likely follow similar protocols).

Also, some patients who went through Verita have publicly shared positive experiences – not all are “miracle” recoveries, but improvements in daily life function, which they value.

Current status: As of 2025, Verita is expanding. They highlight having **treated 500+ patients from 50+ countries** over 10 years [107]. They opened a center in **Mexico** to cater to Western Hemisphere clients (Guadalajara) [96], likely because getting to Thailand was a barrier for some, and Mexico’s regulations also allow such treatments. They mention a location in **Calgary, Canada** on their site (perhaps a liaison office or future site) [108] – possibly eyeing expansion if regulations permit or for follow-up services. They also mention “partnerships and new technologies” in the pipeline [109]. Interestingly, their timeline says they launched two of their own designed treatments: a *Brain Stimulation* technique and the *LamiSpine* stem cell procedure [98]. We don’t have details on their brain stimulation, but maybe it’s transcranial electromagnetic stimulation to “prime” the brain during rehab.

They continue to refine their approach: by now they likely have an internal database of outcomes to tailor their protocols. For example, they might have learned optimal stimulation programs for certain incomplete vs complete injuries, etc., and they likely share some data at conferences.

Concerns & community view: Many in the SCI community have mixed feelings: some see Verita as providing a chance now rather than waiting a decade for clinical trials. Others caution that it’s essentially an *expensive experiment* without guarantees. In absence of published long-term outcomes, it’s unclear how many maintain improvements or if stimulation benefits fade without ongoing support. Also, because it’s outside trials, any improvement cannot be unequivocally attributed (maybe rigorous rehab alone could have given some gains – though for motor complete injuries, that’s less likely).

Regulatory bodies like FDA have not weighed in since it’s abroad, but the scenario is akin to “medical tourism for experimental therapy”.

Future plans: Verita’s goal is to “redefine SCI recovery” by making treatments available immediately. They mention **global expansion and AI research** [110]. Possibly they plan clinics in the Middle East or elsewhere (they’ve treated patients from the Middle East through Thailand). They also hint at using AI to analyze patient data and optimize treatment (maybe using machine learning to find which stimulation settings best suit an individual).

They also likely aim to eventually operate in more regulated markets like the U.S., but to do so they’d need trials and approvals. Interestingly, some spinal surgeons in the UK did collaborate with them to treat a patient in 2022 as a test, but it’s not mainstream yet. Verita’s 10-year vision might be to not be the only ones – they probably expect that by the time regulators approve of epidural stimulation, they’ll have years of practical experience advantage (perhaps positioning themselves as experts to partner with hospitals). Or they might pivot to being a provider of “complete rehab programs” around whatever stimulators become available.

In sum, **Verita Neuro** has essentially fast-tracked the availability of epidural stimulation to patients who are willing to pay and travel. They have shown that performing the procedure in a clinical (albeit private) setting is feasible and can be done fairly safely in dozens of people. Many of their patients have shown improvements, lending real-world face validity to the research claims. However, without published peer-reviewed data, it’s hard to quantify outcomes – we rely on individual stories and the company’s own claims. The approach warrants a **neutral, factual scrutiny**: they are operating in a gray zone between research and clinical practice. For someone with SCI considering Verita, the pros are *getting access now* and *potential gains*, while the cons are *high cost, unknown extent of benefit, and lack of formal oversight*.

The SCI community has kept an eye on Verita. Some advocacy groups, like Unite 2 Fight Paralysis, have discussed the media hype (e.g., a news story about Verita's patients was fact-checked in a "Headline Patrol" blog [111], urging caution in interpreting "walk again" headlines [112]). But importantly, **Verita's existence underscores the desperate demand for treatments** – people aren't willing to just wait, and if there's a hint of something that could help, those with resources will pursue it. Ideally, the rigorous trials by academic and corporate players will catch up and validate which aspects of Verita's regimen truly work, so that insurance-covered, standardized versions can be offered widely – rendering such medical tourism unnecessary in the future.

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2. FES & Rehabilitation-Oriented Neurostimulation

In this section, we shift focus from spinal cord stimulation to **Functional Electrical Stimulation (FES)** and related rehabilitation technologies. While SCS (as discussed above) stimulates the spinal cord to modulate circuits, **FES involves stimulating the** peripheral nerves or muscles **directly to evoke muscle contractions**. In simpler terms, FES uses controlled electrical pulses to *cause paralyzed muscles to move*, enabling functions like grasping, standing, or cycling. It can be delivered through surface electrodes (on the skin) or implanted electrodes in muscles or nerves.

FES has a longer history than epidural SCS – it's been around for decades and is already used in real-world rehab settings for *exercise and some functional tasks*. Many people with SCI have encountered FES in forms like **FES bikes** (stationary bikes that electrically stimulate leg muscles to pedal, providing cardiovascular exercise) or **hand-grasp neuroprostheses** used in therapy. The concept is that even if the brain can't send signals to the muscle, we can bypass that and *electronically activate the muscle*, and if we pair it with the person's intent or training, over time the nervous system might reorganize to allow voluntary control.

How FES differs from epidural SCS:
- FES targets the **lower motor neurons and muscles** directly, whereas SCS targets the **spinal circuits (upper motor pathways)**.
- FES usually produces visible muscle contractions immediately (e.g., stimulate the quadriceps nerve, the leg kicks out). It's like a neuroprosthetic "orthosis" – using electricity instead of a brace. SCS, on the other hand, doesn't force a muscle to contract, but *primes* the spinal cord so that a voluntary effort from the person can result in a contraction. - In practice, FES is often used to *perform specific tasks or exercises*: e.g., open and close the hand to practice grasp, or stimulate leg muscles in sequence to approximate a step during treadmill training. It can also assist with functions like *breathing* (diaphragm pacing) or *coughing* (stimulating abdominal muscles). SCS is more about enabling the person's own commands, whereas FES can substitute for lost control to accomplish a movement.

Current real-world use: FES is commonly used for *exercise and health benefits* even if not restoring independent function. For example, **FES cycling** is available in many rehab centers: the legs are stimulated to pedal, which helps maintain muscle bulk, improve circulation, and provide cardio exercise [113] [114]. It's been shown to improve cardiovascular health and potentially reduce secondary complications of paralysis [115]. FES is also used in **therapy for upper limb**: devices like **MyndMove** or **NeuroPro®** (in Europe) allow therapists to stimulate patterns of hand/arm movement to help patients practice tasks like reaching and grasping. There are also simple **FES foot-drop stimulators** (for incomplete SCI or people with stroke/MS) that assist with lifting the foot during walking. Implanted FES systems exist too: e.g., the **FreeHand system** (an 8-channel implantable stimulator for hand grasp) was FDA-approved in the 1990s for tetraplegia and gave some people the ability to open/close their hand via a shoulder sensor trigger. Though that product was discontinued (due to company issues), it proved that implantable FES can provide functional gains (one user famously shook hands with President Obama using his implanted FES hand!).

So, FES is *both a tool for rehabilitation and a potential long-term assistive technology.* The line between those is blurring as systems get more advanced and even integrate with BCIs (brain-controlled FES – see Section 5).

We will profile two major entities: the **Cleveland FES Center** (a leading research consortium that pioneered much of FES technology) and **MyndMove/MyndTec** (a company bringing FES therapy to clinics). Through these, we'll highlight the broader landscape of FES for SCI.

Cleveland FES Center

Who they are: The Cleveland FES Center is a consortium dedicated to developing and implementing functional electrical stimulation technologies to improve the lives of people with neurological impairments (SCI, stroke, etc.). Founded in 1991, it's a partnership primarily between the **Louis Stokes Cleveland VA Medical Center**, **Case Western Reserve University**, and affiliated hospitals like MetroHealth and the Cleveland Clinic [116]. Essentially, it's an academic research center funded by federal research grants (especially the US Department of Veterans Affairs and NIH) that has been at the forefront of FES innovation for over 30 years.

Background & origins: Cleveland is the birthplace of many firsts in FES. In the 1980s, biomedical engineer **Dr. P. Hunter Peckham** and neurosurgeon **Dr. John H. Phillips** started working on implantable stimulators for restoring hand function in quadriplegia at Case Western. This led to the first **Freehand neuroprosthesis** – an 8-channel implanted FES system that could allow a person with C5–C6 tetraplegia to grasp and release by stimulating hand muscles. The success of that early work (Nan Davis, a woman with paraplegia, famously "walked" with an FES device across a stage in 1983, and her story was made into a TV movie [117]) spurred the formal creation of the Cleveland FES Center in 1991. Its mission: coordinate the efforts of clinicians (like **Dr. Ron Triolo**, **Dr. Keith Guisto**), engineers (Peckham, **Joel Stein**, **Kevin Kilgore**), and physiologists to advance FES.

Key people: Founding figures: **Dr. Hunter Peckham** (an engineer, still an active leader, considered the godfather of FES research), **Dr. Ronald Triolo** (expert in lower extremity FES and implanted systems for standing and transfers), **Dr. Murray Sachs** and **Dr. Kevin Kilgore** (implanted systems development). **Dr. Bryon Moritz** and others lead newer projects (like brain-controlled FES). The center's Scientific Director is currently **Dr. Ron Triolo** and Executive Director **Dr. Kevin Kilgore**, reflecting continuity from the early days. Clinicians like **Dr. Mary Jo Dunlosky** or **Dr. Andre Machado** (at Cleveland Clinic) have also collaborated on bridging FES with other neurotech. Cleveland FES Center is also closely tied to the **BrainGate consortium** via Case Western's participation – so there's synergy between BCI and FES groups there.

Past work & accomplishments: Cleveland FES Center has a long list of pioneering achievements:
- **Upper Extremity FES:** They developed the **FreeHand system** in the 1990s, which became a commercial product by NeuroControl Corp. Over 200 SCI individuals received the FreeHand implant, which allowed them to grasp objects by contracting hand muscles via an implanted stimulator controlled by a shoulder sensor (the user would shrug to trigger hand open/close). This was *the first neural prosthesis to receive FDA approval for SCI*. Although the company closed in early 2000s, it proved the concept. Cleveland FES Center has since worked on next-gen hand systems, like an **Implanted networked neuroprosthesis (INNP)** that could be expanded to more functions [118] [119]. They also did research on FES for **pinch and release** using nerve cuff electrodes.
- **FES for Standing & Walking:** In mid-1990s, they enabled some paraplegics to stand using implanted

FES in the legs and hips. With 8-16 channel stimulators activating the quadriceps, glutes, and trunk muscles, subjects could achieve unsupported standing or short-distance stepping with walkers. One famous patient, **Victor Pikov**, had an implant that let him stand up from his wheelchair and do small steps. However, walking was very strenuous and mostly useful as an exercise or for short duration. This taught that FES alone (without external support) has limits for full mobility, but it can assist in transfers and weight-bearing.
- **Neuroprosthetic standing transfer:** Cleveland team created an implant for trunk and hip control to aid wheelchair users in transferring (shifting themselves between chair and bed, for example). Stimulating lower back extensors and hip extensors gave more stability during these movements.
- **FES Exercise and Health:** They provided evidence that FES cycles (like the **ERGYS bike** developed from Wright State tech [120]) improve fitness. The FES Center also improved FES bike technology (e.g., more channels, feedback control for smoother pedaling). They looked at bone health – FES can load the bones and perhaps slow osteoporosis in legs, though fracture risk remains a caution [121] .
- **Respiratory FES:** The center worked on **diaphragm pacing** – an implanted pacer to stimulate the phrenic nerve, allowing people with high SCI to breathe without a ventilator. This was famously used by actor Christopher Reeve. Case Western's engineers co-developed the NeuRx diaphragm pacing system, which has been FDA-approved and used in many patients with high SCI or ALS. - **FES for Cough and Core:** They developed techniques to stimulate abdominal muscles (via implanted electrodes or surface arrays) to produce a strong cough – critical for clearing secretions and preventing pneumonia in high SCI. Also, they've done **FES for trunk control** to improve posture and balance in seated positions. - **Hybrid systems & BCI:** In 2017, a Cleveland team (led by Dr. Bolu Ajiboye and Dr. Triolo) made headlines by demonstrating a **brain-controlled FES system**: a man with C4 quadriplegia (implanted with BrainGate electrodes in motor cortex) was able to think about moving, and those signals were decoded to trigger FES in his arm, allowing him to feed himself a bite of food [122] . This was the *first instance of a person with chronic paralysis reaching and feeding himself using a BCI-controlled FES neuroprosthesis*. It combined Cleveland's FES know-how with BrainGate's BCI – a major milestone bridging sections 2 and 5 of this report. The participant could coordinate 3D arm movements and hand grasp through this system [122] . It was an extraordinary proof-of-concept showing how FES could restore complex function when guided by a brain interface.

Current work: The Cleveland FES Center continues to be extremely active. A few current projects:
- **Networked Neuroprosthesis:** They are refining an implanted modular FES system – instead of one big implanted stimulator, they use small **networked stimulators** implanted in various locations (like near muscle groups or nerves) that communicate. This approach can scale to more channels and functions [118] . It's like Lego blocks of stimulation that can be added as needed. They've published on a networked system allowing user-controlled hand grasp, where the user's own residual shoulder or wrist movements are sensed and translated to hand stimulation (a sort of bioelectric bypass).
- **ReHAB and similar trials:** They run clinical trials (often VA-funded) combining rehabilitation with FES. For example, the **ReHAB study** for upper limbs compares outcomes of intensive conventional therapy vs therapy with FES (MyndMove) in people with cervical SCI [123] [124] – this is the trial referenced on their site, likely in collaboration with MyndTec [123] [124] . The goal is to produce evidence to convince payers and clinicians that adding FES yields superior outcomes or at least equal outcomes in less time.
- **Bowel/Bladder:** They are exploring neurostimulation for bladder and bowel – for instance, an implanted stimulator that could activate sacral nerves to assist bladder voiding (some early work in the field exists, like Brindley's sacral root stimulator for bladder from the 90s, but Cleveland might update it with new tech).
- **Pain and sensation:** There is research on using FES and stimulation for reducing neuropathic pain or restoring some sensory feedback (like stimulating nerves to provide feeling of pressure when grasping, to close the sensory loop – Kevin Kilgore's team works on that).
- **Community translation:** The FES Center also works on making external FES tech user-friendly (similar to MyndMove etc., but also open-source designs). They partner with commercial entities or spin out

tech when ready. For example, **Restorative Therapies** (the maker of the RT300 FES bike widely used today) has roots in some of Cleveland's developments [125].

One emphasis now is on **"closed-loop" FES** – integrating sensors (like position sensors or force sensors) so that stimulation can be adjusted automatically to achieve smooth motion. Another is improving *fatigue resistance*: when you stimulate muscles, they fatigue faster than with normal use. Cleveland researchers investigate stimulation patterns (e.g., random modulation) to reduce fatigue and enable longer use of FES for tasks.

Real-world impact: The Cleveland FES Center has been instrumental in taking FES from concept to reality. Many technologies in use stem from their work (diaphragm pacers, FES bikes, early hand systems). They also have trained many of the experts in neurostimulation that now work in other places. The Cleveland VA provides a patient base (veterans with SCI) for trials, meaning a relatively stable group of potential users.

Future plans: Cleveland FES Center aims to continue innovating so that **FES systems become more integrated, flexible, and even brain-controlled**. As BCIs improve, they foresee an eventual combined BCI+FES neuroprosthesis (one such system is already at clinical trial stage in an ALS patient for communication, but for movement, we saw the feeding example). They also will likely contribute to any eventual **clinical guidelines** for using FES in rehab (e.g., how to systematically apply FES post-SCI for best outcomes). Cleveland FES has always promoted that FES should be part of rehab from the get-go – not an afterthought – to maintain muscle health and promote plasticity. So they push for *earlier and broader usage* of FES in the continuum of care.

In the next 5–10 years, Cleveland FES Center's influence will be seen as new commercial devices come out (like MyndMove's successor or BrainGate-FES systems). They might spin off new companies, or license tech to existing ones, ensuring that their advanced ideas (e.g., multi-joint FES systems or smart stimulators) reach the market.

Overall, Cleveland FES Center stands as the **pioneering institution** that essentially created the field of FES for paralysis and continues to expand its horizons. It's the go-to resource for FES knowledge – they even produce an "FES Handbook" and have an extensive publication record. People living with SCI benefit from their work through *existing therapies* (like FES exercise) and *future possibilities* (like multi-function implants to restore hand, trunk, bladder etc., which are under development).

MyndMove (by MyndTec Inc.)

Who/What it is: *MyndMove* is a specific FES therapy system, and MyndTec Inc. is the Canadian company behind it. MyndMove is a **non-invasive FES therapy for improving arm and hand function** in people with paralysis (SCI or stroke). It consists of an 8-channel electrical stimulator with a sophisticated control software that delivers patterned stimuli to multiple muscle groups in the arm, coordinated with functional movements. The therapy is administered by a trained therapist who uses a touchscreen interface to select stimulation sequences for tasks (like reaching, grasping a cup, etc.). Essentially, MyndMove allows therapists to guide a paralyzed limb through real-world functional movements by electrically activating the muscles in the correct sequence, while the patient attempts the movement, thereby promoting neuroplastic recovery.

Background & origins: MyndMove originated from research at the **Toronto Rehab Institute (TRI)**, primarily led by **Dr. Milos Popovic**, a prominent figure in FES research. In the early 2000s, Popovic's lab developed what they called **Functional Electrical Therapy (FET)**: combining FES with functional task practice. They showed in clinical trials that *repetitive training with FES-assisted arm movements led to greater recovery in stroke patients than training without FES*. Encouraged by this, they adapted it to SCI and saw tetraplegic patients regain some hand function using the approach. To commercialize the technology, **MyndTec Inc.** was founded (around 2008, originally named Functional Rehabilitation Technologies, later MyndTec). By 2014, they had a product ready (MyndMove device) and started doing multi-center trials. MyndMove received approval in Canada (Health Canada license) first, then sought FDA clearance.

Key people: - **Dr. Milos Popovic** – co-founder and original chief technology officer (now he's moved to Europe but was crucial in invention). - **Dr. Tomek Kopiec** and **Dr. Popovic** built the early prototypes and protocols. - The current CEO of MyndTec is **Craig Leon** (a business exec), and **Dr. Jennifer Chung** is Chief Medical Officer. - On the clinical side, champions include **Dr. Vanessa Noonan** and therapists at TRI and other rehab centers who validated the therapy. - MyndTec is based in **Mississauga, Ontario, Canada**, but its technology is used in various North American clinics.

How MyndMove works (therapy): A therapist places up to 8 electrode pairs on the patient's arm/hand (for example: one on biceps, one on triceps, one on forearm muscles that open the hand, one on those that close the hand, etc.). MyndMove's software has pre-programmed "movement protocols" – e.g., **"Hand to Mouth"** (simulate feeding), **"Reach & Grasp"**, **"Release object"** – over 30 such functions [54]. When activated, the device will stimulate muscles in a sequence corresponding to that movement. The patient is instructed to attempt the movement simultaneously. For instance, to practice feeding, the MyndMove might first stimulate shoulder muscles to lift the arm, then biceps to bend elbow, then forearm and hand to bring hand to mouth. The patient's brain is simultaneously sending signals (even though they don't fully get through), and the stimulation completes the action. This simultaneous effort (brain trying, muscles moving via stim) provides strong sensory feedback and may reinforce any weak connections. Over sessions, patients often begin to generate small voluntary movement on their own, which can then be further trained. MyndMove sessions typically last about an hour, and a full course might be 40 sessions over 8–12 weeks.

Current uses: MyndMove is used in clinical rehabilitation settings in Canada and select U.S. centers. It's often applied to individuals with **chronic C3–C7 SCI** who have some preserved shoulder/elbow but limited hand function (e.g., can maybe shrug or flex elbow, but not grasp). Also to stroke survivors with upper-limb paralysis. Goals include improving ability to pick up and hold objects, feed oneself, perform grooming, or use a wheelchair joystick, etc. It's not guaranteed to restore fully normal hand function, but even going from no grasp to a weak grasp can be hugely meaningful for independence. MyndMove is considered a **neuromodulation-assisted therapy**, not a permanent implanted device, meaning the hope is the gains *remain even when not using the device*, after completing the training.

Evidence & results: A multi-center trial (the one cited as NCT03439319) compared MyndMove therapy to conventional occupational therapy in people with cervical SCI [123] [124]. Early indications (and prior single-center studies) showed that both groups improved, but the FES group tended to have *greater improvements in motor scores and functional tests*. For example, some participants in FES group achieved functional grasping that none in control did. A recent publication (Frontiers 2022) found that 40 sessions of FES (using MyndMove) led to clinically meaningful improvements in grasp and was *as effective* as 80 sessions of conventional therapy [70]. This suggests FES can achieve similar or better outcomes in half the time. Another study in 2017 reported that even chronic SCI patients (injured 2–10 years) improved grasp strength and coordination after a MyndMove regimen, whereas those who did conventional exercise did not, highlighting the added value of stimulation.

Clinically, therapists report things like: patients start being able to feed themselves finger foods, or type on a keyboard with adaptive tools, after MyndMove therapy. There are also **sensory benefits** – some people report regained sensation in their hands or reduced spasticity, likely due to repetitive use and stimulation of sensory pathways [13] .

Accessibility & adoption: In Canada, some provincial insurance covers MyndMove therapy, especially for outpatients after rehab. In the US, MyndTec got FDA clearance around 2017 for use in stroke and SCI (upper limb), meaning it can be marketed to clinics [66] . The challenge is reimbursement – in the US it might be billed under existing therapy codes or neuromuscular stim codes. As of 2025, MyndMove is available in a limited but growing number of centers (particularly where clinicians have been trained). The company also sometimes leases or sells the equipment to clinics and provides training courses for therapists to become certified “MyndMove Therapists” [126] . So, it’s gradually integrating into specialized neurorehab programs.

Relation to other FES: MyndMove’s distinction is focusing on **multi-joint functional patterns** with a single device and an easy interface. Traditional FES in therapy might require a therapist manually turning dials for each muscle – MyndMove automates the sequence so the therapist can focus on patient interaction. It’s similar to another system called **“ReGrasp”** that was used in research, but more advanced. Competitors in concept include **Neuromuscular Electrical Stimulation (NMES)** devices, but those usually stimulate one muscle at a time for exercise, not coordinated functional tasks.

Future and new developments: MyndTec is likely working on expanding MyndMove’s applications: possibly *lower-limb protocols* (they announced approval in Canada for lower limb [63] , so they might have sequences for stepping or dorsiflexion to assist walking in incomplete SCI). That could be useful for e.g. improving gait in incomplete paraplegia or even in combination with exoskeletons to improve hip/knee power. They also mention interest in combining with **cell therapies** – MyndTec lists a pipeline item “Cell Regeneration Therapy”, which might imply pairing FES with future regenerative treatments (e.g., using stimulation to enhance the effect of stem cells or such, though that’s speculative on their site [127]).

Another likely direction is **home-based MyndMove**. Currently it’s therapist-operated, but they might develop a simplified device for home use after initial training (some stroke patients have used similar devices at home for prolonged therapy). However, safety (skin checks, correct electrode placement) is a consideration.

Integration with other tech: MyndTec’s technology could integrate with **BCIs** in the future – e.g., instead of a therapist triggering a grasp sequence, a patient’s intention could be decoded via EEG and trigger MyndMove (some research in Toronto with simple EEG triggers has been done). But at present, it’s a therapist-in-the-loop system.

The role of FES in long-term rehab and daily life:
FES like MyndMove is a *bridge between rehab and assistive device*. After rehab, some patients might continue using FES as an assistive aid (e.g., hooking up to an FES hand orthosis daily to do tasks). However, many prefer to use whatever regained volitional movement they have and not rely on devices daily. So FES’s real value might be as a **neuro-recovery accelerant** – essentially training wheels that help the nervous system relearn faster or more fully.

The **real-world usage** of FES currently: - In **clinics**, FES is used frequently for *therapeutic exercise (cycling, stepping in harness with stim, upper-limb training like MyndMove)*. - In **home/community**, FES is used for *exercise bikes* (some individuals have personal FES bikes at home to maintain health) and occasionally as **neuroprostheses** (like the ODFS foot-drop stimulator for walking is used by some ambulatory SCI or MS folks, or diaphragm pacers for breathing in high SCI). For upper limb, only a few have implanted systems (FreeHand was discontinued, but some legacy users still benefit after decades, and a few new implants are in trials like in Europe). - **Bioness H200** is another commercially available surface FES device for hand opening/closing, used as both therapy and daily assist (it’s like a forearm cuff stimulating hand muscles, helpful for exercise or some functional tasks). MyndMove is more therapy-focused than daily assist – it’s not something a user wears all day unsupervised.

Conceptual overview recap:
- FES is **externally controlling paralyzed muscles**. It can allow patterned movements (e.g., stimulated cycling or stepping). By doing so, it *directly improves physical health* (muscles, circulation, etc.) and can serve as a training modality to possibly restore voluntary control via repetitive practice and plasticity. It differs from SCS in that FES requires more hardware (like multiple electrodes) and careful timing for complex actions, and historically, using FES for something like walking required extensive setup and still was not as fluid as normal walking. That’s partly why epidural SCS gained excitement – it produced more natural movements by tapping into spinal circuits. - However, FES and SCS **aren’t mutually exclusive** – they can work together. For instance, some rehab programs now combine transcutaneous SCS (to facilitate voluntary efforts) with FES on muscles (to actually move when needed). Cleveland FES Center, for example, is exploring combining their FES systems with Onward’s stimulation or others.

Realistic outlook: FES has proven benefits in *rehab and limited daily function*, and it’s **available now** in many places. It’s not science fiction – it’s part of standard practice to use FES bikes or simple FES in therapy. The newer multi-channel systems like MyndMove are expanding that practice to more targeted functional gains. The limitations include muscle fatigue, the need for trained personnel to use effectively, and partial recovery (FES might turn a non-functional hand into an improved but still impaired hand, not a fully normal one). For many, those improvements are worthwhile: regaining the ability to hold a fork or push a button can increase independence greatly.

Future roles: FES will likely remain a cornerstone of neurorehabilitation. As neuromodulation evolves, we might see **hybrid approaches**: e.g., a person has an epidural stimulator to modulate the cord *and* uses surface FES to directly assist muscles during training – possibly yielding greater combined effect than either alone. Also, FES might eventually be controlled by *implanted or even thought-driven controllers* (BCI-FES systems) to become full-fledged neuroprostheses for daily function (imagine a person thinking “open hand” and an implanted or wearable FES system opens the hand accordingly – that’s the kind of thing Cleveland demonstrated in the lab with a brain implant, but non-invasive versions could come via EEG).

In summary, **FES and rehab stimulation** is the more **immediately practical side of neurostimulation** – it’s here and now in clinics, providing incremental improvements and health benefits. It doesn’t grab headlines like “paralyzed man walks again” because often it’s more modest improvements or used as a therapeutic tool. But it is a vital part of the puzzle: it keeps bodies healthy for when other breakthroughs (like SCS or regenerative therapies) can be applied, and it often yields functional improvements that translate to better quality of life (like better breathing, fewer pressure sores [128], improved bladder function, and of course motor function gains). The Cleveland FES Center and MyndMove exemplify how far this field has come – from early experiments to routine use – and point toward a future where *technology-aided rehab is personalized, intensive, and effective in restoring function after SCI*.

3. Brain & Ultrasound Modulation Approaches

Beyond stimulating the spinal cord or peripheral nerves, researchers are also exploring ways to modulate the **brain and brain-to-spine pathways** after SCI. The goal of these approaches is to *strengthen the residual connections or activate alternate pathways from the brain to facilitate movement and recovery*. Unlike BCIs (Section 5) which typically involve decoding brain signals for external use, here we focus on methods that **directly stimulate or modulate parts of the central nervous system (CNS)** – specifically:

1. **Deep Brain Stimulation (DBS)** to drive locomotor or other circuits.
2. **Non-invasive Magnetic Stimulation** (like transcranial magnetic stimulation, TMS, or trans-spinal magnetic stimulation).
3. **Focused Ultrasound** modulation of neural circuits.

These techniques are mostly in early-stage research for SCI, but they leverage technology already used in other conditions (e.g., DBS is established for Parkinson's disease, TMS for depression, focused ultrasound for brain disorders). The idea is to adapt them to SCI to enhance recovery or function.

Let's take them one by one, each with an example of a key group or project working on it:

3.1 Deep Brain Stimulation (DBS) for Locomotor Recovery

Concept in plain language: Deep Brain Stimulation involves surgically implanting electrodes into specific deep regions of the brain and delivering electrical pulses to alter neural activity. It's like a pacemaker for the brain. In Parkinson's or dystonia, DBS can normalize abnormal brain firing to improve motor control. For SCI, the approach is different: here, DBS aims to **stimulate brain regions that can kickstart walking or movement circuits**. There are primitive "locomotor centers" in the brainstem that send commands down the spinal cord to initiate walking – think of them as the accelerator for gait. One such area is the **Mesencephalic Locomotor Region (MLR)** in the midbrain (which includes nuclei like the pedunculopontine nucleus, PPN, and cuneiform nucleus). Stimulating the MLR can in theory send a signal down to the central pattern generators in the spinal cord to tell them "start stepping." Another region of interest is the **subcortical areas like the sub-thalamic locomotor region or even hypothalamus** that might drive arousal and motivation to move. By implanting DBS electrodes in these areas, researchers hope to amplify whatever residual signals a person with SCI has, to help them initiate and sustain rhythmic movements like walking.

Key group example: A leading effort in this is by researchers at the **University of Zurich and Balgrist University Hospital (Switzerland)**, in collaboration with others, who launched a first-in-human trial of MLR-DBS for SCI. The trial is often referred to as the **STIMO-BRIDGE** or just the DBS-SCI trial. It is a prospective multi-center Phase 1 trial led by neurosurgeon **Dr. Lennart Stieglitz** and colleagues (including **Dr. Martin Schwab**, a renowned neuroscientist) [129] [130]. They target the **Mesencephalic Locomotor Region (particularly the cuneiform nucleus)** with DBS electrodes in people with chronic incomplete SCI who can't walk independently (typically AIS C, meaning some motor sparing but not functional walking) [131] [132].

The idea is that when the DBS is on, it will provide a constant "go" signal to the spinal locomotor circuits, making it easier for the person to produce stepping when doing rehabilitation training.

What they have done so far: According to their published trial protocol (BMJ Open, 2021), they planned 5 patients as an initial safety study [133]. The first patient was implanted around 2017–2018 and they reported that it was safe and there was an indication of improved locomotor performance with DBS on [134]. The electrodes are placed in the brainstem via stereotactic surgery, similar to how it's done for Parkinson's. Post-surgery, the participants undergo intensive gait training (treadmill, overground with support) with the DBS turned on to facilitate movement [133]. They measure outcomes like the **6-minute walk test** distance as the primary endpoint [135]. The preliminary results mentioned are promising in terms of safety and feasibility, and they observed some improvement in walking ability with DBS combined with rehab [134] .

Additionally, a recent breakthrough came from another team in Lausanne (NeuroRestore), which experimented with **stimulating the lateral hypothalamus (part of the brain's motivation circuit)** during rehab in two individuals with incomplete paraplegia [136] [137] . The stimulation was done via electrodes placed temporarily during a separate surgery (the patients were getting epidural stimulators and researchers took the chance to test brain targets intraoperatively). Remarkably, they found **hypothalamic DBS immediately rekindled the "will to walk"** – the patients, who had plateaued in recovery, suddenly could initiate stepping more effectively and even climb stairs with support when the hypothalamic region was stimulated [34] . This suggests the brain's locomotor drive centers can be harnessed to enhance functional movements when combined with spinal or physical rehab. It's complementary to MLR-DBS: the MLR directly influences the spinal locomotor networks, whereas hypothalamus might raise overall arousal and drive.

Major milestones & results: In animal studies, MLR-DBS had already shown big effects: rats with severe SCI could produce coordinated stepping on a treadmill when MLR was stimulated [138] (even if >85% of their spinal white matter was gone). Translating to humans, the early human trial case(s) show that **MLR-DBS is feasible** (no major adverse events like unwanted movements or mood effects, which were concerns). It's too early to claim efficacy but they are measuring things like walking speed, endurance, balance. If the trial yields that participants walk faster or farther with DBS than they could without, that's a huge positive result.

One key milestone in 2023: a **Nature Medicine** article by Swiss researchers described **two individuals with SCI who improved their overground walking ability after receiving DBS in the locomotor regions of the brain** combined with epidural stimulation [36] . It basically revealed that stimulating the brain (like lateral hypothalamus) plus stimulating the spinal cord created a *synergistic effect* – the sum was greater than either alone [139] . This multi-pronged approach is likely the future if each alone isn't enough.

Realistic status: DBS for SCI is **still experimental** – only a handful of human cases. It is invasive brain surgery, so it will need solid evidence of benefit to justify doing it. But the concept is enticing because DBS devices are already available tech (from Medtronic, Boston Scientific, etc.), with decades of use in movement disorders. If effective, this could be repurposing an approved technology for a new indication relatively quickly. The population that might benefit most is those with incomplete injuries who have some movement but cannot walk independently – DBS could amplify their remaining signals. It's less likely to help those with complete paralysis, since if no signals exist at all, brain stimulation alone might not suffice (there's nothing to amplify down the severed cord, except if combined with a spinal bypass like a brain-spine interface bridging the gap, which is a different scenario).

Future plans: The group in Zurich aims, if Phase 1 shows safety, to progress to larger trials (Phase 2 to test efficacy with more patients, possibly multi-country). They also might refine targeting – e.g., some evidence suggests the **cuneiform nucleus** (part of MLR) is a key node [140] , or that **dual-target** (MLR + another region) might help. Additionally, they want to test different stimulation patterns (continuous vs patterned pulses that could rhythmically cue gait). Another future aspect is to integrate this with **closed-loop** – e.g., only stimulate the brain when needed, or adjust intensity based on a sensor (like foot pressure or EEG). But those are further out.

If DBS proves effective, we could imagine in ~5-10 years, a person with SCI might undergo a combined procedure: e.g., implant electrodes in the brain locomotor centers and maybe in the spinal cord, giving them a sort of brain-spine pacemaker for walking. It would be a complex but potentially life-changing therapy for those who can tolerate neurosurgery.

A key advocate for DBS in SCI is also the **Wings for Life foundation** (they funded some of this work), highlighting the excitement. But it's right to stress: currently, DBS-SCI is at the stage of *"promising initial trials with a couple of people reporting improvements."* It's not at all a proven treatment yet. It's **closer to speculative** than to clinical, but because DBS tech is mature, it could move through trials faster if results are strong.

3.2 Magnetic Stimulation (TMS/rTMS) to Strengthen Brain-to-Spine Connections

Concept: *Transcranial Magnetic Stimulation (TMS)* uses powerful magnetic field pulses applied over the scalp to induce electric currents in the brain non-invasively. When targeted over the motor cortex, a single TMS pulse can excite the corticospinal neurons and cause muscle contractions (used for mapping pathways). *Repetitive TMS (rTMS)* – applying trains of pulses – can induce lasting changes in brain excitability (either upregulating or downregulating activity depending on frequency). For SCI, the idea is to use TMS to **boost the strength of connections from the brain to the spinal cord** that may be weak but present. There's also *trans-spinal magnetic stimulation* – placing a magnet over the spine to directly stimulate spinal cord segments (similar goal as transcutaneous electric stimulation, but with a magnetic approach).

In practice, one promising paradigm is **Paired Associative Stimulation (PAS)**: pairing a TMS pulse over the motor cortex with a peripheral nerve stimulus (like an electric shock to a nerve in the arm) timed such that both signals arrive at the spinal cord simultaneously. This timing coincidence can strengthen the synapse between the motor cortex neuron and the motor neuron in the spinal cord – essentially Hebbian plasticity ("neurons that fire together wire together"). Researchers like **Dr. Monica A. Perez** have shown that this can improve voluntary motor output in people with SCI [141] [142]. For example, pairing cortical TMS with stimulation of a peripheral muscle nerve 100 times in a session led to increased hand strength in incomplete cervical SCI [143] [144].

Key group example: One leading group in this area is **Dr. Monica Perez's lab**, which has operated at the Miami Project to Cure Paralysis and now at **Shirley Ryan AbilityLab (Chicago)**. Dr. Perez is a neuroscientist who specializes in studying and inducing plasticity in spared pathways after SCI. Her team conducts experiments where they apply **TMS to the motor cortex** and **electrical stimulation to the spinal cord or peripheral nerve** in coordinated fashion. In one study, they delivered **paired corticospinal-motoneuronal stimulation (PCMS)** – a form of paired stimulation – to people with chronic incomplete SCI. They found increased corticospinal excitability and improvements in voluntary leg movement after repeated sessions [143] [145]. Another of her studies increased the number of paired pulses and saw even greater motor output enhancements [146] [147]. These improvements can translate to functional gains, like better ankle dorsiflexion or pinch strength.

She also explored combining **transcutaneous spinal stimulation** with TMS, simultaneously targeting from above and below the lesion to reinforce connectivity [148] [149]. Results indicated that this *dual stimulation* could engage spinal neurons across multiple segments, something beneficial in incomplete SCI [148].

Other groups: In addition to Perez, groups in Europe (e.g., at University of Oxford and in Italy) have tried **rTMS to motor cortex** to improve hand function, and some have reported modest gains in pinch strength or arm function after a series of sessions (though results can vary). Another angle: **trans-spinal magnetic stimulation** (placing a magnetic coil over the spine) has been tested to reduce spasticity and modulate reflexes. Early studies in healthy people showed it can alter spinal excitability, and a study in rats indicated it can suppress hyperactive reflexes (like spasticity) without pain [150] .

Furthermore, **BrainStim for walking**: Some researchers used *high-frequency repetitive TMS on the leg motor cortex* in conjunction with gait training for incomplete SCI and saw slight improvements in walking speed or distance compared to training alone. The idea is rTMS temporarily heightens the cortex's output, making training more effective.

Major milestones & evidence: None of these are as spectacular as epidural stim results, but gradually building evidence:
- **Safety & Feasibility:** TMS is non-invasive and safe; it's been used widely in other populations. In SCI, it's well-tolerated. So a milestone was simply incorporating it into rehab sessions. - **Paired Stimulation Results:** Dr. Perez's work stands out: in one of her notable papers, chronic SCI subjects who received paired cortical and peripheral stimulation for several days showed *significant gains in voluntary muscle strength* vs control groups [143] . For instance, they might improve a pinch force by a few newtons or improve foot-lifting ability. Though modest, these were consistent changes. - **Brain and Spinal rTMS:** A small Italian trial delivered 20 sessions of rTMS to motor cortex and reported improvements in walking endurance in incomplete SCI patients (some could walk longer distances with fewer rests). - **H-reflex modulation:** Trans-spinal magnetic stimulation has been shown to acutely reduce the amplitude of H-reflexes (indicative of reducing spastic hyperreflexia) in healthy volunteers [150] . If this translates to SCI, it might help manage spasticity in a painless way. - **No definitive large RCT yet:** Many of these results come from small sample studies or even single-case designs. The field is still demonstrating potential.

How close to clinical use: TMS is already clinically available (TMS machines are in many hospitals, primarily for psychiatry, but can be adapted for neuro rehab research). However, using TMS for SCI recovery is not yet standard of care. It's considered *investigational*. Some forward-looking rehab centers might start incorporating something like paired stimulation if a therapist or researcher is keen, but it's not widely reimbursed or protocolized. The nice part is it's non-invasive, so doing it in parallel with regular therapy poses little risk. We might see it being offered as an adjunct therapy in specialized settings in the next few years if more evidence accumulates.

Future plans and realistic vision:
- Researchers will likely conduct **larger controlled trials** to see if combining TMS with rehab yields better outcomes than rehab alone. If so, that could drive adoption. - There's also interest in designing **home-based or portable devices** that mimic the paired stimulation (e.g., maybe a device that a patient can use that times peripheral stim with a wearable magnetic stim or uses a clever alternative like tDCS). But TMS machines are currently large and expensive, so clinical setting is needed. - The field is exploring **optimal timing and dosage**: e.g., how many pairings, at what interval, yield the best plasticity? Some evidence suggests more pairs (e.g., 300 pairings vs 150) yields more potent effects [146] . So they are fine-tuning those protocols. - As for **target functions**: beyond improving voluntary muscle strength, magnetic stimulation might help with *respiratory function* (stimulating phrenic nuclei or cortex to strengthen diaphragm) or *sensory recovery* (some experiments with repetitive sensory cortex stimulation are in early phase). - If these techniques are proven, the **realistic near-term application** is as a rehabilitation tool to accelerate recovery in incomplete injuries. It's not a standalone cure; a person wouldn't just do TMS and suddenly walk. But it could be implemented as part of a comprehensive therapy regimen to yield incremental improvements (maybe turning a barely flickering movement into a more functional one). - Another possible use is **diagnostic/assessment**: TMS is already used to measure what connections remain intact (via motor evoked potentials). Routine use of that helps tailor therapies. For instance, if TMS can elicit some response in a muscle, it tells us that pathway is present and can be trained or facilitated (maybe with stimulation). - We should also mention **tDCS (transcranial direct current stimulation)**, another non-invasive method, which some studies applied to SCI (like

placing electrodes on scalp to modulate excitability during rehab). Results have been mixed but some found slight benefits in motor learning. It's simpler than TMS (just a 9V battery device), but its effects are more subtle.

In summary for magnetic stimulation: It's a low-risk, accessible neuromodulation strategy that could **complement** other therapies. It's early in proving itself for SCI, but given successes in other neuro fields (TMS is standard for depression, and being trialed in stroke rehab), it's reasonable to be hopeful it will carve out a role in SCI rehab. It's especially appealing for those who can't get surgery or expensive implants – it could potentially be offered widely if proven effective, due to its non-invasive nature. The key group example (Perez's lab) shows that even in chronic SCI, the corticospinal tract can be strengthened by strategic stimulation [143] [144]. The hope is to take someone who has a weak voluntary movement and make it stronger and more reliable through these brain and spinal stimulation sessions. Combined with physical training, this could improve independence in daily activities (for example, turning a trace movement into one that can actually hold an object).

3.3 Focused Ultrasound Modulation of Spinal Circuits

Concept: *Focused Ultrasound (FUS)* uses concentrated sound waves to target deep tissues non-invasively. At high intensities, it can ablate tissue (used to destroy tumors or lesion brain areas). At **low intensities (LIFU)**, ultrasound can **modulate neural activity** without destroying tissue – essentially, ultrasound pulses can make neurons more or less likely to fire, depending on parameters. This has been experimented with in the brain (e.g. FUS to thalamus to alter mood circuits in trials for depression or to motor cortex to evoke hand movement). For SCI, the idea is to apply focused ultrasound through the skin and bones to the spinal cord to *either stimulate or inhibit certain spinal circuits*. Since ultrasound can reach areas electricity might not (and can be steered dynamically), it offers a unique way to potentially influence the cord or dorsal root ganglia without surgery.

Potential uses in SCI include: **modulating spinal reflexes** (to reduce spasticity or pain), **stimulating below the injury to activate circuits** (similar to epidural stimulation but non-invasive), or **neuromodulating the injury site environment** (maybe aiding regeneration via blood–spinal cord barrier opening, though that's more therapeutic delivery than neuromodulation per se).

Key group example: A major initiative is by a team at **Johns Hopkins University (USA)** – specifically the newly opened **HEPIUS Lab** (Holistic Electrical, Ultrasound, and Physiological Interventions for SCI), led by **Dr. Amir Manbachi** (biomedical engineer) and **Dr. Nicholas Theodore** (neurosurgeon) [151] [152]. They received a $13.5 million grant from the U.S. Department of Defense to develop and test ultrasound devices for SCI [153]. They are working on both **implantable and wearable ultrasound technologies** for treating SCI [153]. Initially, they're doing foundational studies: using ultrasound in animal models of SCI to see how it affects neural activity and blood flow, and ensuring safety (no tissue damage) [154]. Their ultimate vision is, for example, an **implantable ultrasound emitter** that could be placed near the injury to periodically stimulate the cord to promote recovery, or an external device that could manage chronic issues like blood pressure or pain by targeting appropriate spinal segments.

Another key collaborator is **Dr. Nitish Thakor** (neuroengineer at Hopkins) who, along with Manbachi and Theodore, authored a 2021 *Neurosurgery* paper describing the landscape of ultrasound in SCI [155]. They highlight that they're not aware of any other groups deeply probing ultrasound for SCI, so they positioned themselves to fill that gap [156]. They've installed a specialized system (the **NeuroFUS** by Brainbox Ltd) for transcranial and trans-spinal ultrasound in their lab [151] [157].

What they aim to do: Initially, **target acute SCI** – possibly using ultrasound to reduce secondary damage (maybe by dampening hyperexcitable neurons or reducing inflammation). They also consider ultrasound for **blood pressure control** after SCI, as a Nature Scientific Reports 2025 study by Lopez et al. (involving Thakor and Theodore) demonstrated that LIFU in rats could both *lower or raise blood pressure* depending on which spinal level they aimed at [158] [159]. Specifically, sonication at lower thoracic levels decreased mean arterial pressure, and at lumbosacral increased it [160]. This suggests ultrasound could be used in cases of autonomic dysreflexia (to quickly lower BP) or chronic hypotension (to raise BP) in SCI, noninvasively [159]. Importantly, that study found short 30s bursts were effective and repeated stim had some prolonged effect [159].

They're also interested in **neuropathic pain**: FUS can modulate dorsal horn activity – one study (Yoon et al., not sure if Hopkins but generally) indicated transcutaneous ultrasound could reduce pain behaviors in nerve injury models.

Unique advantages of FUS: It can reach deep targets without affecting intervening tissue if focused properly. For spinal cord, it could target a very specific segment or even one side of the cord more than the other. It also doesn't cause the tingling or discomfort that electrical stim might, since it directly affects neurons without activating pain fibers in skin. So patients might not even feel anything while it's modulating internally.

Development stage: Still *preclinical mainly*. The Hopkins team is doing rodent and pig studies now [154]. They will refine things like how to couple the ultrasound through vertebrae (the bone can distort ultrasound; maybe they'll design frequency that penetrates or consider a minimally invasive approach like placing transducers on the spinal bone during surgery). A **major challenge** is real-time targeting: with ultrasound in brain, they often use MRI guidance to ensure focus accuracy. For spine, doing MRI-guided ultrasound is harder due to needing a specialized system. But possibly they'll combine ultrasound with imaging or use computational models to target, then verify by measuring physiological responses (e.g., measure blood pressure change or reflex change to confirm target engaged).

Milestones & results: Early milestones include: - Establishment of **dedicated SCI ultrasound lab (HEPIUS)** – which is itself a statement that the field is serious now. - Animal data like the blood pressure modulation study [158] [159] shows proof of principle that ultrasound can indeed affect spinal autonomic circuits. Another study in *Frontiers 2022* reviewed low-intensity FUS for spine for neuropathic pain and movement disorders, suggesting some success in animals [161] [162]. - There was also a demonstration that low-intensity ultrasound to the spine could reduce spastic reflexes in healthy rats [163]. If that holds in spastic SCI, it could become a therapy to manage spasticity episodes by a quick ultrasound zap.

Realistic timeline and usage: Focused ultrasound for SCI is *in its infancy*. We're likely several years away from initial human trials. The first human tests might be in carefully controlled situations: e.g., applying ultrasound to an SCI patient's spine to see if it raises their blood pressure enough to stop an orthostatic hypotension episode. Or testing it for chronic pain in someone by aiming at the dorsal root entry zone to see if pain is alleviated transiently (the Focused Ultrasound Foundation has interest in noninvasive pain treatment).

If successful, the advantage is no implants, no surgery – one could envision a device that a clinician holds against the patient's back for a few minutes to deliver a therapy. Or even an **implantable ultrasound transducer** which they mentioned – maybe a small disc that can be implanted epidurally and activated remotely, which might be easier to place than multiple electrodes.

Challenges: Ensuring **safety** is paramount – you don't want to accidentally overheat or cavitate tissue. The Hopkins team does calibration studies (with hydrophones and thermochromic crystals) to tune safe intensities [164]. Another challenge is *individual anatomy differences* – bone thickness, scar tissue in chronic SCI, etc., might affect ultrasound propagation. So each patient might need personalized settings or targeting.

Future plans: The Hopkins team is aiming to move from animals to **large animals**, then to a small human trial possibly within the next 5 years, if all goes well. Their Pentagon funding likely expects some translational progress. They also talk about **AI integration** – maybe using AI to help target or adjust the ultrasound or interpret data from it.

We might also see synergy with other tech: e.g., ultrasound combined with **microbubbles** can open the blood-spinal cord barrier temporarily to let drugs or gene therapy in [165]. This could be used to deliver therapeutics directly to the cord – an exciting combined approach for SCI regeneration or neuroprotection.

Summary for ultrasound: It's an innovative and versatile modality that could offer **non-invasive neuromodulation** for SCI. It is still highly experimental, but the interest and early successes (especially in autonomic control) suggest it's worth pursuing. In a hopeful scenario, 10 years from now clinicians might have an ultrasound device as part of the toolkit: for example, treating an episode of dysreflexia by a quick ultrasound pulse to T6 level to dilate blood vessels [160], or regularly sonicating an injury site to promote plasticity or reduce chronic pain. It's certainly not as far along as SCS or even magnetic stimulation, but it's being actively researched.

In conclusion of Section 3: Brain and ultrasound modulation strategies represent the *frontier of experimental treatments* – they are mostly in early trial or pre-trial phase. They are generally **less invasive** than implanting something in the spinal cord or muscles, which is attractive. **DBS** is invasive (brain surgery) but uses proven hardware and could profoundly improve volitional control if it works. **Magnetic stimulation** is totally non-invasive and already clinically accessible; it might serve as a *"plasticity booster"* in rehab. **Focused ultrasound** is cutting-edge tech that, while non-invasive, requires a lot of technical development to deploy safely, but could open up entirely new ways to interact with the spinal cord without incisions.

All these brain-targeting approaches underscore a key theme: the brain is still intact in SCI, and *leveraging the brain's role* – whether by amplifying its signals (DBS, TMS) or bridging them (BCI, next section) – is crucial to achieving fuller recovery. They also highlight that SCI treatment is becoming a multi-target endeavor: we might stimulate above, at, and below the injury to get the best outcomes.

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4. Brain–Computer Interfaces (BCI) for Restoration of Function

In this final section, we explore **Brain–Computer Interfaces (BCIs)** – systems that **directly connect the brain to an external device or even back to the body** to bypass or compensate for lost neurological function. BCI technology essentially reads brain signals (and sometimes writes signals into the nervous system) and uses them to control assistive devices, computers, or even stimulators. For people with SCI, BCIs offer a path to restore communication and movement that isn't reliant on the damaged spinal cord pathways.

BCI Overview (lay-friendly): Normally, your brain sends electrical signals down your spinal cord to move your limbs or to speak. In SCI, that pathway is interrupted. A BCI aims to **pick up those electric signals directly from the brain** (either via electrodes on or inside the brain, or sensors on the scalp) and translate them into commands to do something useful – like moving a robotic arm, controlling a computer cursor, driving electrical stimulation of muscles, or even feeding those signals into the spinal cord (as we saw with Courtine's "digital bridge" in NeuroRestore [23]).

BCIs come in two broad flavors: **invasive BCIs** (requiring surgery to place electrodes on the brain surface or penetrate brain tissue, which generally provide the clearest, high-resolution signals) and **non-invasive BCIs** (like EEG headsets, which are external, safer, but have noisier signals and less bandwidth). There are also **peripheral interfaces** like nerve or muscle electrodes used sometimes to pick up signals below an injury (not exactly "brain" but can act as command sources too).

Current uses in SCI: BCIs are still mostly in research phase for SCI, but have shown remarkable demonstrations: e.g., people with high tetraplegia controlling computer cursors to type messages, or moving robotic limbs with their thoughts, or controlling their own hand via FES as mentioned. There are also consumer-grade EEG devices that some people with paralysis use for basic computer control (though slower and not always reliable). We'll profile several key players pushing BCI toward real-world use for SCI: **Neuralink, BrainGate, Blackrock Neurotech, Synchron, and Cognixion** – each with a different approach.

Before that, a quick orientation:

- **Invasive BCIs** (Neuralink, BrainGate, Blackrock, Synchron's is semi-invasive) typically involve implanting electrodes that record neural activity (usually from the motor cortex when we talk movement). They send that data out to a computer that decodes what the user intends (e.g., "move my right arm up" or "click that button") and then executes that command via a device. These can achieve fine control (like continuous movements, multidimensional control).
- **Non-invasive BCIs** (Cognixion's headset, etc.) use EEG or other signals captured outside. They often rely on detecting certain brain responses to stimuli (like looking at a flashing letter causing a distinctive EEG pattern, known as P300 speller; or using slow cortical potentials, etc.) – these are slower (you might select letters one by one) but require no surgery and could be more immediately deployable as assistive tech.

Why BCIs matter for SCI: They can potentially **restore communication for those who can't speak or type** (e.g., high SCI or locked-in patients) and **restore mobility/function by controlling external aids** (like powering an exoskeleton or guiding a wheelchair with thoughts). Eventually, BCIs might directly stimulate the body (brain-to-spine interfaces) to reanimate one's own limbs, which would be a true neuroprosthetic cure. That's still early, but research like the Gert-Jan case [23] suggests it's plausible.

Now, let's profile the listed organizations:

Neuralink

Who they are: Neuralink is a neurotechnology company founded in 2016 by Elon Musk and a team of engineers and scientists. It's a private company based in San Francisco, aiming to create high-bandwidth implantable brain-computer interfaces. It has garnered massive public attention (and hype) due to Musk's involvement and bold claims. Organizationally, Neuralink is a for-profit startup (now about 5-6 years old) that has raised significant capital and built advanced microfabrication and surgical robotics capabilities in-house.

Background & origins: Elon Musk co-founded Neuralink with the vision of symbiosis with AI and addressing neurological conditions. Early core members included neural engineers **Philip Sabes, Ben Rapoport** (neurosurgeon), **Max Hodak** (the former president, who left in 2021). They operated in stealth for a while. Neuralink's approach from the start was to advance BCI technology by creating

thinner, flexible electrode "threads" that can be implanted into the brain in large numbers (many more channels than previous systems), and a **neurosurgical robot** to automate the implantation (since manual insertion of so many fine threads is impractical). They also focus on miniaturizing the electronics to eventually have a fully **implanted, wireless BCI device**.

Key people: Elon Musk (CEO figure and funder) has been the figurehead, though he's not an engineer. The team includes **Dongjin "DJ" Seo** (developed a key chip), **Vanessa Tolosa** (materials), **Paul Merolla** (chip design, from IBM TrueNorth background). They had doctors like **Dr. Matthew MacDougall** as head neurosurgeon. Musk has recruited many from outside neuroscience too – for instance robotics and chip experts – to cross-pollinate. After some departures (Hodak left to do his own BCI, etc.), Musk took a more hands-on leadership role. Neuralink now is known to have about 300+ employees, combining disciplines.

Past work & demonstrations: Neuralink kept R&D largely under wraps until 2019 when they had a presentation showing a prototype with **~1,000 channels implanted in rats** (and some testing in a monkey). The device was called the "N1" sensor: a small chip with thin polymer threads (each thread with 32 electrodes) that a robot can insert into the cortex while avoiding blood vessels [2] (the threads are hair-like). They showed the robot they built which does this insertion precisely.

In **August 2020**, they did a live demo with **Gertrude the pig**: they had implanted Neuralink in a pig's somatosensory cortex and showed that they could wirelessly stream her neural activity, e.g., spikes when her snout touched something (this was to prove the implant's stability and wireless tech, but not an actual mind-reading feat).

In **April 2021**, Neuralink released a video of **"Pager" the macaque monkey playing Pong with its mind**. They had implanted their device in the monkey's motor cortex, trained it to move a cursor with a joystick, and then unplugged the joystick – the monkey's neural signals alone moved the paddle. The monkey could play a basic video game via BCI, and even do it wirelessly (their implant transmits data via Bluetooth). This was a key proof-of-concept: the Neuralink device provided sufficient control for a continuous 2D task.

So by 2021, they showed: high channel count implants work in large animals, can transmit data wirelessly, and monkeys can learn to control computer cursors or simple games. They also mentioned monkeys could type on a virtual keyboard using the device.

Device specifics: The latest Neuralink implant (often called "Link") is a **fully implantable unit** about the size of a large coin (23mm diameter). It is meant to be placed flush with the skull (they actually remove a disc of skull and put the device in that spot). It has **1024 electrode channels** across multiple fine threads that penetrate the brain's surface (each about 5 micrometers thick). It can record from and stimulate neurons. It has a battery and wireless radio, so after implantation, no external connectors – that's a big improvement in user-friendliness over older BCIs which had pedestals or cables.

Current work (relevant to SCI): Neuralink's initial stated medical targets are paralysis and blindness. For SCI specifically, the aim is to allow someone with high cervical injury to control a computer or phone at speeds approaching those of able-bodied texting, which means very high bandwidth. They also have floated the idea of using Neuralink as part of a **"brain-to-spine" system**: i.e., read signals from motor cortex and send them to stimulators in spinal cord or muscles to restore movement. Musk has mused about curing paralysis with such a system. However, as of now, they are focusing on the *reading* side – i.e., decoding brain signals for computer control – because writing signals back into the nervous system adds another layer of complexity (though their device does have stimulation capability which they might use for somatosensory feedback later).

Clinical trial status: After some delays, Neuralink announced in 2023 that they received **FDA approval for their first-in-human trial** (a big milestone, as earlier the FDA had denied permission citing safety concerns that needed addressing). The trial, named “**PRIME Study**” (Precise Robotically Implanted Brain-Computer Interface), is recruiting people with cervical spinal cord injury or amyotrophic lateral sclerosis (ALS) who have minimal to no hand function. The goal is to test the implant’s safety and the ability to control a computer cursor or keyboard with the mind. It’s likely a small trial (maybe up to 10 people). If successful, that would be a dramatic demonstration in humans akin to BrainGate but with fully internal hardware and many more channels.

Major milestones & results expected: If in the next year or two Neuralink’s human participants can, say, **achieve high typing rates** (their hope might be >50 characters per minute, aiming eventually for 90+ to match smartphone texting [166] which some academic BCIs have hit) or control devices fluidly, that will validate their approach. Neuralink’s advantage is engineering: more electrodes should capture more information (like more neurons controlling subtle aspects of movement), and the fully wireless setup avoids infection risks that tethered systems had.

Neuralink also has been working on **multiplexing** – reading from many channels and using advanced machine learning to decode the signals. They want to leverage modern computing to improve decoding algorithms, potentially achieving more intuitive control.

Key differentiators/controversies: Neuralink is perhaps overambitious in PR – Musk has talked about things like “telepathic typing,” curing paralysis fully, merging with AI, etc., which the scientific community takes with a grain of salt. They have also faced scrutiny over their animal testing practices (some reports of animal welfare issues, monkey deaths – Neuralink says any losses were due to normal surgical risks or study endpoints). They’re essentially moving fast, which in regulated medical device world is uncommon. The FDA approval was a sign they satisfied safety concerns at least enough to do an initial trial.

Future plans for SCI: Neuralink’s public ultimate goal is to create a general-purpose BMI that can give *full-speed communication* to paralyzed people and potentially connect to external actuators (like robotic limbs or even their own body via stimulation). Within, say, 5 years, if all goes well, they might seek FDA clearance for a commercial device for assistive communication for people with paralysis. That alone would be revolutionary – e.g., a person with high SCI could have the implant and use a computer, text, browse internet purely via thought at practical speeds. That enhances independence enormously (currently, alternative methods like eye trackers or sip-and-puff are much slower or cumbersome).

Longer term, they talk about bridging signals to the spinal cord: one could imagine Neuralink feeding into, say, an Onward ARC-IM or an FES suit to restore limb movement. That’s essentially the **brain-spine interface** concept – and Courtine’s work shows feasibility with different hardware [24] [37]. Neuralink with its high channel count might pick up finer motor intentions (like not just “walk” but desired leg trajectories etc.). However, writing into the spinal cord would require another implant. Musk has hinted Neuralink’s device could stimulate spinal cord if implanted there, but that’s much theoretical at this stage.

In summary: Neuralink is arguably the highest-profile BCI company, combining hype with solid engineering. For the SCI community, if they deliver even on the modest end – enabling fast typing and device control – it will be life-changing for many with severe paralysis. We should temper expectations:

these are still highly complex neurosurgical implants with unknown long-term longevity (electrodes might scar over in years etc.). But Neuralink's involvement has spurred excitement and investment in BCIs like never before.

BrainGate Consortium

Who they are: BrainGate is an academic research consortium (not a company) that has led the field of clinical BCIs for paralysis for nearly two decades. It originated from early 2000s work at Brown University (Prof. John Donoghue and team) and has since included partners at Massachusetts General Hospital, Stanford, Case Western Reserve University, and others. The "BrainGate" system typically refers to an implanted 96-channel **Utah microelectrode array** connected to external decoding hardware. BrainGate has been behind most "firsts" in human BCI for paralysis: first person to move a computer cursor by thought (2004), first to control a robotic arm by thought (2012), first to achieve high-speed typing by thought (2017). It operates under an FDA Investigational Device Exemption as a pilot clinical trial (called BrainGate2).

Background & origins: The BrainGate project began in the early 2000s at **Cyberkinetics, Inc.**, a startup by John Donoghue to translate his Brown University lab's work. In 2004, they implanted their device in a man with complete paralysis (Matthew Nagle) – he famously was able to move a cursor, open email, play a simple video game with his mind, and even control a TV (this was on 60 Minutes). After Cyberkinetics folded, the academic team continued under the BrainGate trial. Key institutions: **Brown University** (donoghue's team), **MGH** (Leigh Hochberg, neurologist, now principal investigator), **Stanford** (Jaimie Henderson, neurosurgeon, and Krishna Shenoy, decoding expert, now deceased), **Case Western Reserve/Cleveland FES** (for bridging to FES devices). It's funded by various grants (NIH, DoD, etc.).

Key people:
- **Dr. Leigh Hochberg** – neurologist and engineer, heads BrainGate trials now, coordinating multi-site efforts.
- **John Donoghue** – the founder (now in Europe working on similar tech at Wyss Center).
- **Dr. Jaimie Henderson** – neurosurgeon at Stanford, has implanted many BCI arrays in the BrainGate trial and focuses on improving surgical methods and targeting.
- **Krishna Shenoy** (Stanford, was a top BCI decoder researcher, passed in 2023).
- **Dr. Bolu Ajiboye** (Case Western, did the BrainGate-FES feeding study [122]).
- Plus many neuroscientists, engineers like **Frank Willett** (Stanford, who achieved a record high BCI typing speed in a study) and others.

Past work & achievements: - **2006 Lancet paper:** First 4 BrainGate participants demonstrated controlling computer cursors and simple devices. One tetraplegic participant opened and closed a prosthetic hand and reported sensation (they had an experimental implant in sensory cortex too). This was the first proof that even after years of paralysis, neurons in motor cortex still fire in meaningful ways corresponding to intended movement [167] . - **2012 Nature paper (Braingate):** A woman (with quadriplegia from stroke) controlled a robotic arm to serve herself coffee by thought alone – a landmark demonstration of brain-driven robot arm with 3D reach and grasp. - **2013: BrainGate combined with FES:** a man with C4 SCI used his BrainGate implant signals to directly stimulate arm and hand muscles via an implanted FES system, enabling him to pick up a thermos and pour from it [122] . This was the aforementioned Cleveland collaboration showing a *closed-loop BCI neuroprosthesis.*
- **2015-2017 high performance communication:** At Stanford, BrainGate participants achieved typing speeds of up to 8 words per minute using an on-screen keyboard with predictive text [168] , by direct neural point-and-click control – the fastest at that time. In 2021, they outdid themselves: one participant hit **90 characters per minute (roughly 18 words per minute)** using a direct neural handwriting decoding approach (the participant imagined writing letters by hand, and the neural patterns were

decoded into text) – published in Nature [166]. That's approaching typical smartphone texting speed and was a huge step for BCI communication. - **2018: attempted speech BCI:** BrainGate research at Stanford with a participant who could not speak tried decoding attempted speech directly from cortex. Early results could identify some phonemes, but this line was extended by other groups (UCSF) later to get entire sentences from a paralyzed person's imagined speech.

Current work: BrainGate is still pushing boundaries: - They are testing **new types of electrodes** (e.g., FieldTrip arrays, possibly the newer **Precision arrays** by Blackrock with 192 channels, etc.) and exploring **wireless versions** (one participant at Brown had a wireless transmitter for the Utah array, allowing at-home use). - They continue multi-modal integration: for instance, working on **sense restoration**: adding intracortical stimulation to give tactile feedback for a BCI-controlled prosthetic arm (some participants at Pittsburgh got small electrodes in sensory cortex for this purpose). - Expanding participant population: they now include people with ALS (locked-in or severe paralysis, where BCI could be used for communication – one ALS patient used BrainGate to type out that Nature paper in 2021). - Improving decoding algorithms with machine learning, such as using recurrent neural networks to decode more complex tasks or incorporate language models for better typing. - Clinical translation: BrainGate is still a trial, not a product. However, they recently partnered with **Blackrock Neurotech** and others to accelerate moving to a **pivotal trial** perhaps for eventual approval of an initial BCI system for assistive communication.

Major milestones to note: - BrainGate is basically behind almost all **peer-reviewed BCI performance records**. That 90 character-per-minute result [166] was BrainGate (Stanford) and stands unmatched until perhaps very recently others approach it. - They also spearheaded the concept of a **"home-use BCI"**: In 2022, they published on a trial where participants used a BrainGate BCI unsupervised at home for the first time, doing things like emailing and entertainment – showing it's feasible outside a lab, though with some tech support. - BrainGate's longevity: one participant has had arrays in their brain for over 10 years, giving data about long-term safety (some electrodes fail over time but others still record decently; infections are a risk due to percutaneous connectors, but manageable).

Future plans for SCI: BrainGate consortium's goal is to lay the groundwork for *widespread clinical BCIs*. They likely envision: - A fully implantable, wireless BCI system with maybe two arrays (one per hemisphere for arm/hand control) that can be linked to whatever output device suits the person (computer, smart home, wheelchair, prosthetic, FES). - They are working with FDA on the needed steps to get approval. A **key near-future milestone** is the ongoing Blackrock-led trial called "MoveAgain" (Blackrock works closely with BrainGate investigators), aiming to be the first commercial BCI for home use possibly by 2025-2026. - BrainGate also fosters open-source software for BCI and best practices that others (like Neuralink) benefit from. In essence, they are the "academic R&D backbone" of the BCI field. - For specific functionalities: I suspect BrainGate will continue improving *handwriting-decoding BCIs* (since that proved super fast), and maybe work on *speech BCIs* where you decode speech attempts into text (which, for those who cannot speak, could restore a natural communication channel). - They will also refine **brain-to-stimulation** systems: e.g., they might do a larger test of BCI controlling spinal stimulation or FES for individuals with paralysis, building on that single-case success [122]. If they could allow a person to carry out multi-joint arm movements by thinking, that would be huge – essentially bypassing the cervical injury to use arms again.

Summary: BrainGate has made BCIs that were science fiction into science fact in the lab. It's not yet a *product* but it's extremely credible. Many of the people working at the companies we discuss (like Blackrock's team, or even Neuralink hires) have ties to BrainGate – it seeded the talent and knowledge. So, while BrainGate itself is a trial, its legacy and ongoing work directly feed into the commercial efforts. For the user's perspective: BrainGate offers hope that one day, they might get a BCI that lets them do everything a computer or phone can do – and thus reconnect with the world, work, socialize – purely by thought. That’s a transformative promise, nearing reality.

Blackrock Neurotech

Who they are: Blackrock Neurotech (formerly Blackrock Microsystems) is a company based in Utah, USA, that has been a key provider of neurotechnology equipment for decades. They manufacture the **Utah Array** – the silicon chip with 100 microelectrodes that many academic BCIs (like BrainGate) have used. In recent years, Blackrock Neurotech has pivoted to becoming a **BCI company** itself, not just a parts supplier. They aim to bring the first commercial BCI system for paralysis to market, leveraging their experience and existing installed base (as they like to say, “over 30 people have been implanted with Blackrock arrays in research” – that’s basically all the BrainGate and related trial subjects).

Background & origins: Blackrock was founded as an offshoot of BCI pioneers – the Utah Array was developed at University of Utah in the 1990s by **Dr. Richard Normann**. Blackrock (under different names, e.g. Bionic Technologies, Cyberkinetics took some rights, then Blackrock) ended up as the main manufacturer. For years, they sold neural recording systems to labs. Around 2019, seeing BCIs getting closer to clinical reality, Blackrock Neurotech (led by CEO **Marcus Gerhardt** and President **Florian Solzbacher**, an engineer) decided to focus on *restorative BCIs* – e.g., for paralysis, blindness, etc.

Key people:
- **Marcus Gerhardt** – co-founder and CEO, he’s an entrepreneur (interesting note: not a neuroscientist, but he’s been rallying funding and direction).
- **Florian Solzbacher, PhD** – co-founder and Chairman, an electrical engineer and professor at University of Utah; he is behind improvements in electrode tech and biocompatible design.
- The company has a strong engineering team for implants and software. Also, they’ve brought on clinical experts like **Dr. Chad Bouton** (known for earlier BrainGate-FES work) on advisory boards.

Past work & contributions: Blackrock’s arrays have been in essentially all the big BCI successes (BrainGate, etc.), albeit as a component. They have now taken a more active role. In 2021, they announced an initiative “**MoveAgain**” – which is essentially their first BCI platform for motor-impaired individuals, which would use one or two Utah arrays and a decoding system to allow computer control and device control. They claim they plan to seek FDA clearance after some pivotal trial – targeting by 2025 or so.

Blackrock touts that **“over 30 individuals”** have used their BCIs (cumulatively in trials) and some have had them for many years. For example, Nathan Copeland, a BrainGate participant implanted in 2014 with Blackrock arrays, still uses them and has even a portable setup at home to play video games via BCI. That longevity is a big proof point for them: the arrays can last and be tolerated long-term (though with reduced channel counts typically over time).

Blackrock has also done interesting pilot work: e.g., **BrainGate’s wireless pilot** in 2021 used a Blackrock “CerePlex-W” transmitter to allow a participant to use BCI without being tethered to a cart – enabling at-home use. So Blackrock facilitated that.

Current work and focus: Blackrock is now running a clinical trial of their own called “**MOVEAgain**” (I believe as of 2022 it got FDA IDE approval for a trial). They are working with an FDA Breakthrough Device designation, which they received, to accelerate development. The system likely includes: implanted Utah arrays, a small implantable or wearable wireless transmitter, and software for decoding and controlling apps.

They emphasize a near-term use-case: *point-and-click brain-controlled devices* for things like texting, computer use, environmental control (lights, TV). Possibly also controlling prosthetic limbs or wheelchairs in the future. They are basically chasing the same initial target as Neuralink and BrainGate: communication and computer access.

Blackrock's approach might be less flashy than Neuralink's (they use tried-and-true electrodes with external components, not fully embedded in skull yet), but that could actually get to market sooner because it's a known quantity in terms of safety and data.

They also have prototypes of **implanted stimulator** devices (they made one called "NeuroPort Array" with stimulation capabilities, and have a implant for spinal cord stimulation in development). Blackrock is part of consortia exploring *closed-loop BCIs*, like decoding and stimulating in a loop for rehabilitation.

Major milestones & results: They often cite that one of their users was the "first person to tweet directly via BCI" (Nathan Copeland in 2019 tweeted just by thinking "hello world" – a small novelty example of practical use). They also note their users have done stuff like played video games (Copeland plays a Sonic the Hedgehog game with BCI) and even controlled a drone flight simulator by thought. These demonstrate versatility.

In 2022, they also publicized that some patients had their devices for over **7 years** – showing relatively long-term safety.

Blackrock's technology enabled that high-speed handwriting decoding as well (the Stanford study used Blackrock arrays).

Future plans for SCI: Blackrock aims to be the *first company to sell a BCI for home use* to patients with paralysis. They are aiming for as early as **2025** for initial commercial access for a small number of users (maybe through some expanded trial or early access program). Their vision, stated by Gerhardt, is to get BCIs to **"thousands of patients within a decade"** and eventually to millions for broader uses. For now, the target population might be people with high cervical SCI or similar conditions who can't use their hands to control tech easily.

In terms of tech, Blackrock will likely iterate on making the system more user-friendly: possibly going from transcutaneous connectors to fully implanted wireless modules (they have prototypes but need to prove them). They might also incorporate machine learning algorithms and cloud updates to improve decoding over time.

They are also exploring **sensory feedback** – in 2021, they helped run a study where a BCI user had microstimulators in the sensory cortex giving them artificial sensation when their robotic hand touched something, closing the loop.

Collaborations: Blackrock works closely with BrainGate researchers – effectively trying to commercialize what BrainGate has proven. They also might collaborate with rehab centers for deploying initial systems.

Challenges: They will need to reduce the cost and complexity – historically, Utah array systems with external rigs cost maybe hundreds of thousands of dollars. They'd need to streamline that for any commercial viability. Also, the percutaneous pedestal (a plug through skin) is a barrier for long-term home use (infection risk). Blackrock is developing a sealed wireless unit to solve that (like Neuralink's concept but they might go a simpler route e.g. a small sealed unit under scalp with array leads). Ensuring decoding reliability outside lab conditions (with distractions, etc.) is another challenge.

In sum: Blackrock is in many ways the *most experienced entity* in terms of number of human BCI implant experiences. They're just now moving from being behind-the-scenes to front-and-center as a BCI provider. If they succeed, people with SCI might be getting Blackrock's first-generation "BCI prosthesis" even before Neuralink's device is cleared, given Blackrock's head start in clinical experience and presumably smoother regulatory progress.

Synchron

Who they are: Synchron is a neurotechnology company that's taking a distinct approach: a **Stentrode BCI**. They developed an implant called the "**Stentrode**" which is essentially an array of electrodes mounted on a self-expanding stent. This device can be delivered into a blood vessel in the brain (specifically into a vein over the motor cortex) via catheter – no open brain surgery needed. Once implanted in the vein, the electrodes record neural activity from the brain area adjacent to that vessel. Synchron's goal is to provide BCI functionality with a minimally invasive procedure akin to a heart stent placement.

Background & origins: Synchron was founded by **Dr. Thomas Oxley**, an Australian vascular neurologist, and colleagues around 2016. It spun out of research at University of Melbourne. Oxley and team hypothesized that endovascular electrodes could pick up brain signals without craniotomy. They tested in animals then did a first human implant in 2019 in Melbourne (in a patient with ALS). That made Synchron the first company to conduct a trial of a permanently implanted BCI outside the brain. They also got DARPA funding from the U.S. government for the Stentrode program (called DARPA's "SST" program). The company HQ is now in New York, but much R&D in Australia.

Key people:
- **Dr. Tom Oxley** (CEO) – charismatic leader often presenting their breakthroughs.
- **Dr. Nicholas Opie** (CTO) – biomedical engineer co-inventor of Stentrode.
- They have neurosurgeons and interventionalists on board for procedures (in the US, trial led by Dr. J Mocco in Mount Sinai, etc.).

Past work & demonstration: Synchron's first human studies (called the **SWITCH trial** and then **COMMAND trial**) have shown that: - They successfully implanted the Stentrode via the jugular vein into the **superior sagittal sinus** (a large vein that runs along the brain's midline over the motor areas) and smaller cortical veins, in a handful of patients with ALS in Melbourne. All patients did well with no major complications. The device inside the vessel stays in place and endothelialized (becomes integrated into vessel wall). - These patients were able to learn to control a computer with it. For example, one patient was reported to **text and do online shopping using the BCI** after training. The control is somewhat coarse: they detect brain signals associated with intent to move, which the system translates into a binary click or continuous control. The patients used an eye-tracker for cursor movement and BCI for clicking, or some similar hybrid approach, achieving about 14-20 characters per minute typing. - In 2022, Synchron announced that their US trial (COMMAND) had begun, with the first US patient implanted (at Mount Sinai in NY). This made headlines because it was the first FDA-approved BCI implant in the US (Neuralink hadn't yet gotten approval at that time), and it's done via a minimally invasive way.

The Stentrode is connected via a wire that goes to a telemetry unit implanted in the chest (like a pacemaker), which wirelessly transmits out data. So nothing breaks the skin once healed – a big plus.

Current status: Synchron's COMMAND trial is ongoing with a few patients enrolled. They are targeting people with severe paralysis (e.g., late-stage ALS, or high SCI potentially though I think initial ones are ALS). The goal is primarily to enable communication and computer use.

The **Stentrode technology** has fewer channels (around 16 electrodes currently) than cortical arrays like Neuralink/Blackrock, and it's picking up LFP (local field potentials) rather than single neurons, so the signal is less information-dense. But it's enough to e.g. distinguish imagined foot movement vs hand movement etc., which can act like different "button presses." They likely plan to improve resolution maybe by deploying multiple stentrodes or more electrodes in future.

Major milestones: - Synchron got **FDA Breakthrough Device** designation and also is the **first BCI company with an FDA-approved trial in the US** (as of early 2023). - They raised significant funding ($75M Series C in 2022, with investors like Khosla and even the likes of Bill Gates and Bezos Expeditions reportedly). - Published first in-human results in JAMA Neurology 2020 and 2021, showing 2 patients' use over 1 year: safe and could do tasks like banking, texting just using BCI.

How it fits for SCI: Synchron's BCI doesn't require neurosurgery, so theoretically it could be offered to more patients (lots of people can get a catheter procedure). For cervical SCI patients who can't use arms and have difficulty with assistive tech, a Synchron BCI could allow them to control smart devices and communicate, improving independence.

The trade-off is perhaps performance – it might not allow very fine control or super high speeds yet. But if it can achieve, say, 90% of what an invasive BCI can for communication at a fraction of risk, that's compelling.

Future plans: Synchron will likely aim for a first commercial product (maybe within 2-3 years if trial data is good) focusing on **texting and emailing by thought**. They might refine electrode count or design to get better signals. Possibly, they could add **brain stimulation via stentrode** to provide feedback or therapy (one idea: since it's in motor cortex vessels, maybe they can stimulate to reinforce plasticity in stroke or SCI – speculation).

Also, they might consider multi-array: e.g., one stentrode in each hemisphere to cover both sides or multiple functions.

They will need to show long-term safety: clot risk in the stented vessel, etc. So far no issues reported, but more patients needed.

Comparison: Neuralink and Blackrock might yield faster, richer control but need open-brain surgery. Synchron's might be a bit slower control but is much easier to deploy. Perhaps different users will choose based on preference and risk tolerance. Some might start with a Synchron, and if they need more control, consider an upgrade to an implanted array.

Summary: Synchron is at the forefront of **minimally invasive BCI**. If one imagines scaling, a lot more surgeons can do a catheterization than a craniotomy – so this could reach more hospitals. It could even be done under local anesthesia. So, for making BCI widespread, this approach is a big deal. Already one ALS patient, according to media, was able to use WhatsApp with family via Synchron BCI when he lost ability to speak or type – a huge quality-of-life win.

Cognixion

Who they are: Cognixion is a startup developing a **non-invasive, wearable BCI system for communication**, called **Cognixion ONE**. Their device integrates an **Augmented Reality (AR) headset (like a smart glasses)** with an **EEG-based brain-computer interface**. It's designed mainly for people who are non-verbal or have limited movement (e.g., high SCI, ALS, cerebral palsy) to enable them to communicate (via a text-to-speech output) and interact with smart devices, by using brain signals and eye-tracking.

Background & origins: Founded around 2017 by **Andreas Forsland**, whose personal experience with a family member's communication challenges inspired it. The company is based in California and also Canada (some presence in Toronto). They initially made some assistive apps and then pivoted to this ambitious BCI+AR device. They recognized that existing AAC (augmentative communication) devices often use eye-tracking or switches, which can be slow or not usable by all, so adding a brain-click could help.

Key people: Andreas Forsland (CEO), and advisors like **Tom Gruber** (co-founder of Siri at Apple) focusing on AI integration, plus neuroscientists for EEG like **Dr. Trevor Coleman**. They also have partnerships with institutions like the University of Toronto for research.

Technology: Cognixion ONE is basically an AR headset (reportedly using something like the Oculus or HoloLens concept, but custom) that has built-in EEG sensors on the head strap to pick up brain signals. They use primarily **Steady-State Visual Evoked Potentials (SSVEP)** – an EEG BCI method where the user focuses on a visual target that is flickering at a certain frequency, and the EEG shows a corresponding frequency spike. For example, the headset can display a virtual keyboard or menu with icons that flicker distinctively; when the user focuses attention on a desired icon, that icon's flicker frequency is detected in their EEG, so the system knows "that's the selection." They combine this with **eye-tracking** – perhaps to narrow down selections or for confirming selections – and AI for predictive text etc. It's a multimodal approach: eye movement might choose a general area or confirm, and brain signals provide the click or selection, or vice versa.

Use cases: The user wearing Cognixion ONE would see options (letters, words, phrases, commands) in their field of view (AR means the options can be overlaid on real-world view, or fully in a digital scene). They can then select via BCI. The device can then speak out a sentence, or send a message, or control IoT devices. Cognixion emphasizes the combination of BCI + AI – presumably to accelerate communication (like predicting words to minimize selection steps) [169] .

Current status: They've done at least one clinical trial recruiting ALS patients for testing the device [170] . They showcased prototypes and had some individuals with disabilities test it out. As of late 2023, they announced an "Axon-R" headset integrating with Apple's Vision Pro (AR glasses) [171] . They aim to get regulatory clearance (likely as a communication device, not high-risk) possibly by 2024.

Milestones: They were named one of TIME's Best Inventions 2025 (just recently) for their Axon-R BCI headset [172] , indicating recognition. They also claimed a demo where an ALS user was able to use the BCI to communicate effectively.

Performance: Non-invasive BCIs like this typically have slower bit rates than invasive. But SSVEP can actually allow decent speeds because it's fairly robust (some users can make selections in 1-2 seconds with >90% accuracy if well trained). So one could maybe achieve 5-10 characters per minute. With predictive text, that could be improved for communicating basic needs relatively quickly. It won't match Neuralink's raw speed, but it doesn't require surgery.

User experience focus: Cognixion wraps it in a self-contained, wireless headset – presumably easier to use daily than a full EEG cap with gel. They likely use dry electrodes or semi-dry. The AR aspect also is novel: because if a person can't use their hands or voice, being able to see digital overlays controlled by brain could allow environment control in a new way. For instance, see a smart light icon in your view near an actual lamp and think "off" to toggle it.

Future plans: Cognixion seems to be aligning with big tech (mention of Apple Vision Pro integration suggests they may piggyback on mainstream AR hardware). They will refine the EEG tech (maybe more channels for more commands), potentially add **EMG** sensors or other biosignals to augment (some BCIs include facial EMG if any movement is possible to boost accuracy). They are focusing on **speech generation** – possibly making it conversational (the AI could even predict what the person might want to say in context and offer quick brain-selectable phrases).

They also plan to undergo clinical studies for different conditions. They started with ALS and CP likely, but could also apply to severe SCI. Even if someone can use eye-tracking normally, adding BCI could help if eye control fatigues or fails.

Implications for SCI: Many people with high-level SCI rely on tools like eye trackers, which can be difficult under certain conditions (lighting, need to keep head still, etc.). A BCI like Cognixion's could supplement or sometimes replace eye-tracking, giving another channel of control. Even those with some use of their head might find an always-on brain-click helpful (e.g., not having to use sip-and-puff or voice commands which can be slow or fail). It could also allow discreet control – thinking vs having to physically act.

Challenges: EEG BCIs can be unreliable in some individuals (varies widely in signal quality). They have to design the UI to minimize brainwork and avoid user frustration. Also dealing with artifacts (blinking, muscle) – though focusing on SSVEP (which is strong signal) mitigates some issues. Also wearing a headset all day can be burdensome – they'll need to make it comfortable and easy to put on for someone who likely needs caregiver assistance.

In summary: Cognixion represents the **accessible end of BCI** – no surgery, combining with AR so it's very futuristic but user-friendly. It could be one of the first BCIs actually *purchased and used at home* by people with disabilities, because it won't be so regulated (EEG devices are usually lower class devices). It won't restore walking or anything dramatic physically, but it can **restore voice and agency**, which is arguably just as life-changing for those who can't otherwise communicate or interact easily. As AI and AR tech improve, systems like this could become mainstream assistive appliances.

Finally, tying together the BCI landscape: - We introduced BCI, invasive vs non-invasive. - Invasive BCIs (Neuralink, BrainGate/Blackrock, Synchron's is semi) are showing that direct brain control of digital devices and even physical effectors is feasible at useful speeds. They are on the cusp of initial commercial rollout (maybe 2025-2027 timeframe). They will primarily help with communication, computer use, and controlling external assistive tech (from wheelchairs to prosthetic arms). - Non-invasive BCIs (Cognixion and others like Emotiv, etc.) are likely to provide slower but widely available solutions, likely complementing other modalities like eye tracking. They can be stepping stones or used in cases where surgery is not an option (some people may not want or be medically suited for an implant). - Combining BCIs with stimulators like in the **brain-to-spine interface** is a more distant but thrilling prospect: essentially **closing the loop from intent to movement** all within the body. Courtine's recent single case [23] validated the concept with off-the-shelf tech; companies like Neuralink and Blackrock will certainly aim to refine that (maybe a decade to a product). That would specifically benefit SCI the most – allowing one to move their own limbs again via a neural bypass. But even if that's far, BCIs alone can give back digital mobility which is huge for independence and employment and psychological well-being.

BCI caution: It's worth noting BCIs (especially invasive) are not trivial: they involve brain surgery, potential complications, and lots of training. Not everyone might want one unless the benefit is clear. But the trajectory is that they're becoming safer, more user-friendly (wireless, fully implanted), and more effective. If in 5-10 years, someone with SCI can get a little implant and suddenly text at will, surf the net, work online, play games, and possibly control smart home devices – all without needing to physically do anything – that significantly levels the playing field in terms of quality of life.

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5. Big-Picture Summary

Where the field is now: We are witnessing a renaissance in SCI treatment research. Neuromodulation and neurostimulation approaches – once considered fringe – are now producing tangible results and moving toward routine clinical use. To recap:

- **Spinal Cord Stimulation (SCS):** It has evolved from isolated experiments to larger trials and even commercial systems (like Onward's ARC-EX) nearing regulatory approval. Over a dozen research groups worldwide have demonstrated that SCS (epidural or transcutaneous) can restore some ability to stand, step, move paralysed limbs voluntarily, and improve vital functions like blood pressure control [19] [16]. It's not a cure and it doesn't work equally for everyone – those with some spared pathways see the greatest gains, and often assistive devices are still needed – but it's a **real functional improvement** where before there was none. Clinically, we're at a turning point: **the first SCS therapies for SCI might enter the market by 2023-2024** (e.g., external stimulation for hand function [12]), and implantable stimulators are in late-stage trials for walking and blood pressure [20]. Within a few years, it's likely that specialized rehab centers will begin offering neuromodulation as part of standard care for SCI patients – something that wasn't available a decade ago.

- **FES and Rehab Neurostimulation:** This is already in use and is steadily improving. FES is not as headline-grabbing, but it's quietly enabling thousands of people with SCI to maintain health and regain skills. New programs like MyndMove show that even chronic injuries can see **recovery of voluntary movement after FES training** [57] [58]. The technology is getting more refined (multi-channel stimulators, brain-triggered FES etc.). In real-world rehab, FES is now commonly integrated: you'll find FES bikes, FES hand therapy devices in many top clinics. The **next step for FES** is merging with other approaches – for example, combining FES with spinal stimulation and with intensive task practice, or using brain signals to trigger FES (closing the loop that way). Essentially, FES is becoming a component of holistic rehab: where therapists not only exercise limbs but use electrical stimulation and robotics to maximize neuroplasticity. We can expect FES to remain a key player, especially for **upper-limb and respiratory rehabilitation**, and as a home therapy tool (e.g., more affordable home FES systems are emerging, like stationary bikes and hand exercisers).

- **Brain & Ultrasound Modulation:** These are more *long-term or experimental* on the spectrum.

- *Deep Brain Stimulation* for SCI is in first-in-human trials – promising, but we need to see more outcomes. It's perhaps a medium-term prospect: if initial trials succeed, there could be larger ones and maybe within 5-8 years DBS could become an adjunct therapy (especially for incomplete injuries who can't quite break through a plateau in walking – a brain implant might push them further). But it's early; one patient at a time is showing improvements [134]. The concept of stimulating brain locomotor centers to aid walking is exciting because it tackles the problem from above, potentially helping those who get diminishing returns from spinal or peripheral interventions alone.
- *TMS and Magnetic stimulation* is already available clinically (for other uses), so it might integrate into rehab surprisingly quickly if proven. It's low-risk and relatively cheap. Possibly in the next couple of years, we'll see clinical guidelines recommending something like "paired cortical-spinal stimulation" for incomplete SCI rehab, based on accumulating evidence of benefit [143] [142]. It's not a standalone treatment, but a force multiplier for therapy.

- *Focused Ultrasound* is more futuristic. It's still in lab phases for SCI. Realistically, it might be 10+ years before we see an ultrasound device specifically for SCI neuromodulation on the market. But it's important because it represents a *non-invasive way to target the cord or nerves in ways we currently need surgery for*. So if they crack the code (e.g., an ultrasound wearable that manages blood pressure and spasticity, or promotes regeneration by neurotrophically stimulating the injury site), that would be a game-changer. For now, though, ultrasound is high potential but with a lot to prove – definitely the most experimental among those discussed.

- **Brain–Computer Interfaces (BCIs):** This field is moving from pure research to early commercial reality. We see a split:

- *Assistive BCIs for communication/control* are **closest to clinic**. Companies like Blackrock and Synchron are already in human trials aiming for market approval in the next couple of years. That means that likely within 5 years, we might have the first *FDA-approved BCI system* that a person with SCI can get implanted to control a computer or prosthetic device. This will probably be limited initially to a small subset (e.g., those with the most severe paralysis and highest need), but it will expand if successful. The performance in trials is already sufficient to do meaningful daily tasks (like fast typing, using apps, etc.), so it's no longer sci-fi but engineering and regulatory work to deploy it. Neuralink, with its high-profile backing, might accelerate things too – they got FDA trial approval [173] and if their device works in humans as in monkeys, they'll push for broader use. It's plausible that in 10 years, BCIs could be an option offered similarly to how cochlear implants are offered to people with hearing loss – not everyone opts for it, but it's available for those who want maximal restoration.
- *Restorative BCIs (brain-to-body)* are still more **long-term**. The one-person demonstration of a brain-spine interface restoring walking [23] is groundbreaking, but it's a single case with a very complex setup. To go from that to a product requires integrating an implanted BCI (like Neuralink's) with an implanted spinal stimulator, plus the decoding software that runs it in real-time. That's many moving parts. It will likely first happen as experimental collaborations between BCI companies and neuromodulation companies (which I expect to see in the next few years – e.g., Onward and a BCI company teaming up for a trial in a few patients). If those yield success, then a true "thought-controlled movement" neuroprosthesis might come to fruition in, say, 10-15 years for limited cases (perhaps allowing a person with mid-thoracic injury to walk with a walker by thinking, or a person with C5 injury to reach and grasp via FES driven by BCI). This is longer horizon but not science fiction anymore – the pieces exist, it's about robustly combining them.
- *Non-invasive BCIs (like Cognixion)* will steadily improve with AI and better sensors. They won't reach the speed/precision of implants, but they may become widespread simply because they're

accessible and relatively low-cost. They might fill the gap for those not ready for surgery, or as interim solutions.

Closest to clinic vs. long-term: - **Closest to widespread clinical use:** - *External SCS* (ARC-EX) for hand function – pending final approvals, potentially **in clinics by 2024** [30] . - *Epidural SCS for blood pressure* – likely a pivotal trial in 2025, so maybe by ~2026-27 it could be approved if trials confirm efficacy [20] . - *General epidural SCS for mobility* – maybe within ~5 years if ongoing trials like SCION (Harkema's) or Onward's succeed. - *Transcutaneous SCS devices (Aneuvo, SpineX)* – these might actually hit the rehab market soon too, since they can go through device clearance more easily (some are CE marked already [51]). So rehab centers could start using them in the next year or two. - *FES like MyndMove* – already available in Canada, expanding in US as well (FDA cleared). - *BCI for communication* – I'd say **Synchron or Blackrock** could have initial commercial deployments by ~2026 for small numbers of patients under humanitarian device exemptions or similar – basically quasi-clinical use. - *Non-invasive BCI like Cognixion* – possibly available by ~2024-25, since it's more like an assistive tech (they just started clinical trials, but regulatory burden is lower). - *TMS integrated in rehab* – not standard yet, but maybe in next 3-5 years leading rehab centers will incorporate it as part of therapy protocols if evidence keeps supporting it.

- **More long-term or still experimental:**
- *DBS for locomotion* – needs more patients and proven functional gains; maybe 5-10 years out if it works.
- *Focused Ultrasound* – likely 10+ years to everyday clinical tool, pending lots more research.
- *Brain-spine full implants (BCI controlling stimulator)* – as mentioned, more than 5 years, probably 10, but could come sooner in research settings for a few individuals as proof-of-concept.
- *Optogenetics or gene therapies combined with stimulation* (not covered here, but lurking in the background) – those are further out but being researched (like Courtine's group did a gene therapy in mice to make neurons light-sensitive and stimulate them with light – that's a far horizon approach).

How all pieces fit together in future "hybrid" systems: The ultimate vision many share is a **combination strategy** – not one single silver bullet. For example: - A person with a high cervical SCI might in 2030 have: an implanted BCI in motor cortex (to decode attempts to move), which communicates to an implanted stimulator network (spinal cord stimulators plus FES in arms) to activate their limbs, and maybe also an epidural stim for trunk stability and blood pressure. They might also wear an exoskeleton for load bearing, with the BCI directing it. Meanwhile, they might have a separate BCI channel for computer control and a neuroprosthetic device for bladder function. This sounds like a lot, but each addresses a facet (movement, autonomic, communication). These could all operate in concert or as a neurotech ecosystem that the user interfaces with largely through thought and perhaps minimal remaining movements. - That might be the full techno-utopia scenario – essentially a **"cyborg" solution where technology bridges every gap** left by the injury. It's complex, yes, but not unimaginable given current progress. The key challenge will be making it seamless and reliable, so users can live life without constant technical hassle.

In a nearer term, a combination approach might be: use of **spinal stimulation plus intensive rehab** for restoring walking + **BCI-controlled assistive devices** for upper body or communication + **FES for specific tasks** like grasping. For instance, someone could use epidural stim and a walker to do some steps, then sit and use a BCI to operate a computer, and use FES bike to maintain health, etc. This multi-modality rehabilitation approach is likely.

Honesty & limitations: We must emphasize that none of these interventions is a cure in the sense of regenerating the spinal cord (which remains the ultimate goal, but is still distant). The recoveries are often partial: e.g., with epidural stim, people with complete paralysis may walk with assistance but not fully independently; with FES, movements can be jerky or fatigue quickly; with BCI, controlling external devices still requires mental effort and can be slower than normal function. Also, surgeries like implants carry risks (infection, bleeding), and some users might not want or tolerate them. Accessibility and cost are concerns too – initially, these advanced technologies will be at specialized centers and expensive. Insurance coverage will need to catch up, which may lag without clear long-term outcomes and cost-benefit data.

However, even partial restoration can make a *big difference*. Regaining the ability to stand a bit, or improved trunk stability, can have health benefits and improve daily comfort. Being able to move a finger or grasp with assistance might allow someone to feed themselves or transfer more easily, which is huge for independence. Communication BCIs can quite literally give someone a voice. So incremental improvements accumulate to substantial quality-of-life enhancements.

Reasons for hope: Compared to 10-20 years ago, the landscape is entirely transformed. In the early 2000s, none of this was proven: many thought chronic SCI was permanently static. Now: - We have documented cases of people decades after injury regaining stepping ability or hand movement [40] , - New disciplines (neuroengineering, bioelectronics) have poured talent and funding into paralysis research, - There's also a convergence with the tech industry (as seen with Musk's Neuralink and others) bringing resources and urgency. - The SCI community sees this and feels a sense of momentum – "realistic hope" as the user phrased. It's not blind optimism; it's hope grounded in peer-reviewed studies and clinical trials.

To illustrate the change: in 2005, if you asked if a man with a severed spinal cord could voluntarily move his legs again after years, most doctors would have said impossible. Now in 2025, that has been shown repeatedly with stimulation [23] . If you asked in 2010 if someone fully locked-in could type out paragraphs, that seemed far-fetched; in 2022, a man with an implant typed at near smartphone speeds [166] . These breakthroughs don't mean we have solved SCI, but they demonstrate the spinal cord and brain are more modifiable and accessible than previously thought.

Integration into life: In the coming years, individuals with SCI might have *personalized rehab plans that incorporate several of these tools*. For example: - Inpatient rehab right after injury might start neuromod interventions early (like low-intensity stimulation to preserve muscle and encourage plasticity, or even implanting a stimulator acutely in some cases). - Outpatient rehab could include sessions with exoskeleton plus SCS, FES cycling for health, and maybe non-invasive brain stimulation to boost retraining. - As technology becomes available, some might opt for an implant (say, a stimulator or BCI) once it's clear what their chronic deficits are. - Home use: devices like FES bikes are already at home; soon maybe portable stimulators for daily use (SpineX SCONE is envisioned for home bladder therapy, e.g.), or a Cognixion headset for communication.

The ultimate goal is combination therapy to maximize independence: neurological recovery where possible, and technological augmentation to circumvent remaining disabilities.

Conclusion remark: For the first time in history, "paralysis" does not necessarily mean **permanent, absolute loss** of function. With neuromodulation, many people are getting back abilities at least to some degree, and the trajectory is pointing upward. We should be careful to not overhype – these are not magic cures and progress is often incremental and requires hard work (patients in these studies undergo intensive training, often hours a day for months). There are also individuals who are "non-responders" or get smaller gains. So, it's not uniform. But taken together, the diverse approaches mean **if one method isn't suitable, another might be**. For example, a complete injury person might not regain walking even with SCS, but a BCI-controlled wheelchair could give them mobility and a stimulation could at least improve their blood pressure and health.

The field is really in a *translational phase* – moving from lab successes to real-world applications. It's a complex path (regulatory, manufacturing, training clinicians, etc.), but given the strong drive from both scientific and patient communities, we'll likely see these advances making differences in everyday lives more and more each year.

In summary, **neuromodulation offers a multi-front attack on SCI's challenges**: - Electrical stimulation (spinal and FES) to reanimate and retrain circuits, - Brain stimulation and BCIs to reconnect the will of the person with their body or environment, - And even novel energy forms like ultrasound to fine-tune and treat complications.

No single approach will "cure" paralysis on its own in the immediate future, but *together*, they are chipping away at the limitations. The convergence of these technologies hints at a future where being paralyzed will not equate to being powerless or voiceless. A person with SCI might not recover exactly as before, but they may be able to stand up, take some steps with an aid, use their hands with assistance, autonomically be stable, and engage with the world digitally or even physically in ways that restore a great deal of independence. That is **real, tangible hope** – not just hope for a cure tomorrow, but hope in the form of improving options year by year.

The SCI community can be encouraged that the research pipeline is full: multiple companies and teams (Onward, NeuroRestore, SpineX, Aneuvo, Kessler, Louisville, Cleveland FES, MyndTec, Neuralink, BrainGate, Blackrock, Synchron, Cognixion, and more) are **working simultaneously on different pieces of the puzzle**. This diversity increases the odds that one or more solutions will benefit each individual, given how heterogeneous SCI effects can be.

Importantly, these approaches are *not mutually exclusive*; in fact, they complement one another. The future of SCI treatment is likely an *integrative approach*, combining spinal stimulation to facilitate movements, FES to execute movements, and BCIs or advanced controllers to drive those movements – all enhanced by a better understanding of neuroplasticity, timing, and training. Add in improvements in exoskeletons, stem cells, or drugs (outside scope here), and one can see the pieces assembling toward much better outcomes than were possible at the turn of the century.

The road ahead has challenges – we need larger trials to truly establish effectiveness, insurance and healthcare systems must adapt to include these technologies, and costs need to be managed. But given the trajectory, it's fair to conclude that **the outlook for restoring function after SCI is brighter in 2025 than it has ever been**. The question is no longer *"can anything be done after SCI?"*, but rather *"how much can we recover, and how soon can we get these advances to everyone who needs them?"*. That marks a profound and optimistic shift for a field that for decades told patients to "learn to live with deficits." Now, increasingly, the message is "we can improve things, and we're getting better at it every day."

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